UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456 CIVIL ACTION: 01-CV-12257-PBS Judge Patti B. Saris
THIS DOCUMENT RELATES TO ALL CLASS ACTIONS	

PLAINTIFFS' CONSOLIDATED OPPOSITION TO DEFENDANTS' MOTIONS TO DISMISS

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I. INTRODUCTION

Defendants seek dismissal pursuant to Fed. R. Civ. P. 9(b), 12(b)(1) and 12(b)(6). No basis for dismissal exists. The allegations of the Master Consolidated Class Action Complaint allege widespread fraudulent manipulation of the published average wholesale price, or "AWP," causing damage to Plaintiffs and the classes they seek to represent. This conduct has been neither sanctioned by Congress nor condoned by regulators; in fact, Defendants have been investigated, and at times prosecuted, for this misconduct. The MCC properly alleges claims for relief under federal law, 18 U.S.C. § 1962(c)–(d), as well as state consumer protection laws. Whether cast as preemption or jurisdictional attacks, Defendants' efforts to invoke the political question doctrine, ERISA preemption, field and conflict preemption, or the filed-rate doctrine, all fail.

II. PRIOR PROCEEDINGS

On September 6, 2002 – and following the entry of a case management order that provided for the consolidation of all actions pending before this Court in MDL No. 1456 – the Plaintiffs filed a 164 page, 465 paragraph Master Consolidated Class Action Complaint (the "Complaint" or "MCC"). The MCC amends the claims and allegations in all complaints then pending before the Court and coordinated as part of MDL No. 1456, as well as any class actions subsequently transferred to the Court. Case Management Order No. 2, ¶ A ("CMO 2"). The MCC adds some new Defendants not previously sued in AWP litigation, omits other Defendants,[1] and clarifies that the MCC seeks relief for overcharges in the private insurer market as well as overcharges incurred by private end-payors in the form of co-payments made under Medicare Part B.

[1] During July and August of 2002, Plaintiffs' counsel reviewed the claims against all existing and potential Defendants. Some of the Defendants who were previously named in one or more of the consolidated actions were omitted from the MCC. Since that time, Plaintiffs' counsel have dismissed without prejudice some of those Defendants from the underlying actions. Defendant Boehringer moves for dismissal based on a purported failure to comply with Local Rule 15.1. Boehringer Mem. at 3. This rule applies in instances where a party seeks leave of Court to add an additional defendant, requiring any motion for leave to amend be served upon the potential new parties 10 days in advance of the filing of any motion for leave to amend. In the instant case, CMO 2, endorsed by the Court on July 23, 2002, expressly provides for the filing of a Master Consolidated Complaint amending all of the individual complaints consolidated into MDL No. 1456. Thus, no motion by Plaintiffs for leave to amend was necessary.

In November 2002, all Defendants moved to dismiss. In three separate orders entered in November, the Court ordered Defendants to limit the length of their common memorandum to 40 pages despite multiple requests by Defendants for a more lengthy common brief. On November 25, 2002, all but four of the Defendants joined in a revised Consolidated Memorandum In Support Of Defendants' Motion To Dismiss The Master Consolidated Class Action Complaint ("Defs.' Mem."), and they filed 17 separate Defendant-specific memoranda. Defendants Bristol-Myers Squibb, Oncology Therapeutics Network Corp. and Apothecon, Inc. (collectively "BMS") as well as Defendant, B. Braun Medical, Inc. ("Braun"), filed two additional memoranda purporting to join the consolidated memorandum and raising additional arguments.[2] This Memorandum addresses all Defendants' arguments.

III. THE ALLEGATIONS OF THE COMPLAINT

The MCC is brought by nine individual plaintiffs, four third party payor plaintiffs and twenty-one associational plaintiffs, all acting on behalf of themselves and a proposed nationwide class of consumers, self-insured employers, health and welfare plans, health insurers and other end payors of prescription drugs (the "Class"). The MCC has three general parts: the general allegations (¶¶[3] 131-182, 329-342); the Defendant-specific allegations (¶¶ 183-328); and a statement of the claims for relief set forth in seven counts (¶¶ 343-465).

A. General Allegations Of AWP Fraud

Prescription drugs are dispensed to patients by or through different types of medical providers, including physicians, retail pharmacies, home infusion companies, hospitals and other medical providers. ¶ 132. Providers regularly submit claims for reimbursement through private channels such as insurers, self-insured employers, other third-party payors or consumers, or through public channels such as Medicare and Medicaid. During the Class Period, Defendants were aware that private insurers and public payors rely on the published average wholesale price

[2] The separate filings by BMS and Braun do not comply with this Court's Order of November 6, 2002.

[3] Unless otherwise indicated, "¶" references paragraphs in the MCC.

to reimburse providers for drugs. Indeed, use of published AWPs to establish reimbursement rates for drugs is an industry-wide practice in both the private insurance sector and in Medicare and Medicaid. ¶ 133.

Several pharmaceutical industry compendia, including the *Red Book*, periodically publish the AWPs for various dosage forms of prescription drugs (the "Publishers"). ¶ 134. The AWP is supplied to the publishers by Defendants for their respective drugs, and the Publishers do not conduct an independent review of the AWPs to ensure their accuracy. ¶ 135. The MCC alleges that Defendants "deliberately set [the average wholesale price] far above the prices that their drugs are available in the marketplace." ¶ 3. The manufacturers "inflate AWP reimbursement rates to enable providers and others to make secret profits through overcharges to patients and their insurers. This, in turn, incentivizes the providers to sell and administer the drugs with the most inflated AWPs, resulting in increased market share and profit" for a particular Defendant. ¶ 3; *et passim*.

The MCC explains how public or private reimbursement schemes are manipulated by Defendants' conduct. As to the private payor side, the inflated AWP works to the benefit of "an intermediary (for example, a pharmacy benefit manager[4] or others) [who can] pocket[] the 'spread' between the AWP and the actual cost that the intermediaries pay for the brand name drugs." ¶ 5.[5] As Plaintiffs explain:

> [I]n a perversion of the type of competitive behavior expected in a market not subject to illegal restraints of trade, the Defendant[s] often promote their drugs not simply with lower prices, but with reimbursement rates based on a fictitious AWP that allows

[4] Pharmacy benefit managers – or "PBMs" – are fiscal intermediaries that specialize in the administration and management of prescription benefit programs. PBM clients include HMOs, employers, preferred provider organizations and other health insurers.

[5] The MCC also alleges in the private payor arena that Defendants know that there are significant discrepancies between (i) the AWP reported by them and therefore the Publishers, and (ii) the prices actually paid by providers and PBMs for those same drugs. ¶ 169. Thus, Defendants incentivize PBMs to place the brand name drugs with the highest-inflated AWPs on the PBMs' formularies. They do this by marketing the spread between the discounted AWP that the PBM agrees to pay retail pharmacies, and the AWP at which the health plans reimburse the PBM. Consequently, Defendants incentivize the PBMs to include in their formularies the drugs with the highest AWPs in order to benefit from the artificial spread. Moreover, the PBMs negotiate rebates with Defendants at a percentage of the drug's list price or AWP. Thus, Defendants further inflate AWPs in order to create additional proceeds that are then passed back to the PBMs as "rebates." ¶¶ 170-71.

> purchasers and intermediaries (including providers and PBMs) to make inflated profits - - and the Defendant[s] to increase their market share at the expense of Plaintiffs and the Class. [¶ 6.]

On the public payor side, Medicare reimbursements are based on the same published AWPs used industry-wide. Thus, for "drugs reimbursed by Medicare Part B . . . providers benefit by pocketing the 'spread' between the AWP and the actual cost that they pay for the drugs[,]" and the manufacturers also "provide chargebacks, rebates, hidden price discounts and/or unlawful financial inducements, including free samples to further increase the provider's spread and, therefore, their incentive to prescribe a particular" Defendant's product. ¶ 4.[6]

The MCC further alleges that Defendants "actively conceal, and caused others to conceal, information about the true pricing structure for the prescription drugs, including the fact that the AWPs for the drugs are deliberately overstated." ¶ 7. In short, the MCC alleges that Defendants have manipulated the AWP systems in an unlawful manner by fraudulently and deceptively reporting inflated average wholesale prices. The AWPs for the drugs at issue were simply fabricated in furtherance of Defendants' scheme to generate profit spreads to providers, PBMs and others and to increase Defendants' profits at the expense of Plaintiffs and the Class members. ¶ 137. (This conduct is sometimes called Defendants' "AWP Scheme".)

B. The Government Investigations Into Defendants' AWP Scheme

The MCC alleges that the fraudulent reimbursement scheme engaged in by Defendants is prohibited under federal and state law and is the subject of aggressive federal and state investigations and prosecutions. The MCC alleges that Congress and regulators of federally-

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[6] The Complaint further alleges that Defendants intentionally published AWPs for Covered Drugs solely to cause Plaintiffs and the Class members to overpay the co-pay for their drugs. Defendants created and perpetuated this scheme so that the medical providers who purchased these drugs at a low cost would bill patients and their insurers at the inflated AWPs and earn a substantial profit from the "spread" between the real cost and the various AWP-related reimbursement rates. Because Defendants controlled the published AWPs, Defendants knew and understood that they could manipulate the providers' profits from Plaintiffs and the Class. The purpose of artificially inflating the providers' profits was to create an illegal kickback to the providers, funded by Plaintiffs' and the Class members' overpayments. ¶¶ 158-61.

Defendants also used free samples as a means of lowering the price, ¶¶ 162-64, and provided and/or arranged for many other non-public financial inducements such as volume discounts, rebates, off-invoice pricing, free goods, credit memos, consulting fees, debt forgiveness and grants. All of these incentives were designed to lower the providers' net cost of purchasing Defendants' Covered Drugs and were not included in the AWPs reported by Defendants. ¶ 165.

funded health care programs have expressed shock at the recent revelations resulting from investigations into drug manufacturer manipulation of stated average wholesale prices, as well as outrage at the vast degree of the inflation, its purposeful use to market spreads in order to change prescription behavior and usage, and its use to disguise unlawful kickbacks and hidden payments.

In this regard, Plaintiffs allege that the United States Department of Justice ("DOJ"), the United States General Accounting Office ("GAO"), the Office of the Inspector General at the United States Department of HHS ("OIG"), and other Congressional subcommittees have been investigating Defendants and other pharmaceutical manufacturers for questionable practices regarding the industry's calculation of AWPs and for offering illegal incentives to providers. ¶ 151. One example of Congress' outrage is found in a letter from Congressman Pete Stark. The Stark letter referred to the AWP manipulation described in the MCC as a "corruptive scheme [that] is perverting [the] financial integrity of the Medicare program and harming beneficiaries who are required to pay 20% of Medicare's current limited drug benefit." ¶ 152. Five "shocking conclusions" were identified in Stark's letter:

> First – Certain drug manufacturers have abused their position of privilege in the United States by reporting falsely inflated drug prices in order to create a de facto improper kickback for their customers.
>
> Second – Certain drug manufacturers have routinely acted with impunity in arranging improper financial inducements for their physicians and other healthcare provider customers.
>
> Third – Certain drug manufacturers engage in the fraudulent price manipulation for the express purpose of causing federally funded health care programs to expend scarce tax dollars in order to arrange de facto kickbacks for the drug manufacturers' customers at a cost of billions of dollars.
>
> Fourth – Certain drug manufacturers arrange kickbacks to improperly influence physicians' medical decisions and judgments notwithstanding the severely destructive effect upon the physician/patient relationship and the exercise of independent medical judgment.

> Fifth – Certain drug manufacturers engage in illegal price manipulation in order to increase utilization of their drugs beyond that which is necessary and appropriate based on the exercise of independent medical judgment not affected by improper financial incentives. [¶ 153.]

That Congress has not sanctioned this practice is also revealed by the actions of Abbott Laboratories, a defendant here, when its related entity TAP Pharmaceuticals agreed to pay $875 million to resolve criminal charges and civil liabilities in connection with its fraudulent pricing and marketing practices for the drug named Lupron,® which included AWP inflation. At a hearing in the criminal matter, United States District Court Judge William G. Young found:

> This has been a gross abuse of the Medicare/Medicaid repayment system, knowing, intelligent. You have demonstrated, and it's all been confirmed in open court, and I don't want anyone forgetting about the fact that this company, not under its present management, knowingly abused the public trust in a most, and I use my words carefully, despicable way.

United States v. TAP Pharmaceutical Products, Inc., No. CR-01-10354-WGY (D. Mass., Dec. 6, 2001).[7] ¶ 156.

Similarly, in stark contrast to Defendants' claims that Congress has in effect immunized their behavior, Defendant Bayer Corporation agreed to settle claims asserted by the U.S. government and 47 states arising from its fraudulent pricing and marketing practices involving AWP manipulation. ¶ 221.

C. Defendant Specific Unlawful Conduct

The MCC sets forth many examples of AWP inflation engaged in by specific Defendants for particular drugs. These allegations, which span 42 pages, are not repeated here. *See* MCC at pp. 44-86. However, the following examples again show congressional condemnation, not condonation:

-- *Regarding Abbott*: "The evidence . . . clearly shows that Abbott has intentionally reported inflated prices and has engaged in other improper business practices in order to cause its customers to receive windfall profits from Medicare and Medicaid when submitting claims for certain drugs. The evidence further reveals that Abbott manipulated prices for the express

[7] The TAP defendants have been sued in a separate class action in connection with their fraudulent pricing and marketing practices for Lupron®. ¶ 155.

purpose of expanding sales and increasing market share for certain drugs." (10/31/00 Letter, Stark to White), ¶ 184.

-- *Regarding Aventis Group*: "The following chart represents a comparison of Hoechst's fraudulent price representations for its injectable form of the drug versus the truthful prices paid by the industry insider . . . . And this underscores the frustration that federal and state regulators have experienced in their attempts to estimate the truthful prices being paid by providers in the marketplace for prescription drugs . . . ." (9/28/00 Letter, Stark to Holmer), ¶ 206.

-- *Regarding Baxter*: "The deliberate manipulation of AWP or WAC prices is a problem that we need to address. The spread between acquisition cost and AWP/WAC is direct profit for customers, and is being used to increase product positioning in the market by certain manufacturers." (Internal Baxter document), ¶ 214.

-- *Regarding Bayer*: "The government's investigation of the allegations . . . revealed that [Bayer] beginning in the early 1990s falsely inflated the reported drug prices – referred to by the industry as the Average Wholesale Price (AWP) . . . ." (1/23/01 Press Release, DOJ), ¶ 221.

-- *Regarding Dey*: "Medicare's reimbursement amount for albuterol was nearly six times higher than the median catalog price" and that "Medicare and its beneficiaries would save between $226 million and $245 million a year if albuterol were reimbursed at prices available to suppliers." (OEI-03-01-00410, March 2002), ¶ 247.

-- *Regarding GlaxoSmithKline*: "If we choose to explain the price increase by explaining the pricing strategy, which we have not done before, then we risk further charges that we are cost shifting to government in an attempt to retain market share . . . . What arguments can we make to explain to congressional watchdogs that we are cost-shifting at the expense of the government?" (Glaxo memorandum, 10/25/94), ¶ 270.

-- *Regarding Immunex*: "The documents further expose the fact that certain of your members deliberately concealed and misrepresented the source of AWPs . . . . However, Immunex's own internal documents indisputably establish the knowledge of the origin of their AWPs and their active concealment." (09/23/01 Letter, Stark to Holmer), ¶ 189.

-- *Regarding Pharmacia*: "The evidence . . . shows that Pharmacia & Upjohn has knowingly and deliberately inflated their representations of the average wholesale price ("AWP") . . . ." (Extension of Remarks of U.S. Representative Pete Stark in the House of Representatives, October 3, 2000), ¶ 299.

D. The Pervasive Damage Caused By Defendants' AWP Scheme

Government payors have not been the only targets of Defendants' AWP Scheme. Private individuals and businesses have also suffered damage as a direct result of Defendants' AWP Scheme. Damage has been directly inflicted on, among others: (i) Plaintiffs and other third-party payor class members who reimburse health care providers or make payments to PBMs for

prescription drugs based upon the AWP; (ii) Plaintiffs and Class members who make prescription drug co-payments under their health insurance plans; (iii) Plaintiffs and Class members who make Medicare Part-B prescription drug co-payments; and (iv) Plaintiffs and Class members who pay in full for prescription drugs. ¶¶ 138-39, 329-32.

E. Plaintiffs' Causes Of Action

Plaintiffs' Complaint contains seven Counts: Counts I-IV for violation of the federal Racketeering Influenced and Corrupt Organizations Act, organized by separate RICO enterprises (*see* ¶¶ 343-450); Count V for Violations of the Consumer Protection statutes of eleven states (*see* ¶¶ 451-457); and Counts VI-VII for declaratory and other relief pursuant to 28 U.S.C. §§ 2201, 2002 (*see* ¶¶ 458-465).

IV. THE APPLICABLE STANDARD FOR DISMISSAL

A. The Allegations Of The Complaint Control

A Rule 12(b)(6) motion should be granted "only if 'it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief.'" *Bolduc v. United States*, 2002 U.S. Dist. Lexis 13830, *3 (D. Mass. July 30, 2002) (quoting *Roeder v. Alpha Indus., Inc.*, 814 F.2d 22, 25 (1st Cir. 1987)). "[The] Court takes as true 'the well-pleaded facts as they appear in the complaint, extending [the] plaintiff every reasonable inference in his favor.'" *Id.* (quoting *Coyne v. City of Somerville*, 972 F.2d 440, 442-43 (1st Cir. 1992)); *see also Greebel v. FTP Software, Inc.*, 194 F.3d 185, 200 (1st Cir. 1999). As a result, a "[m]otions to dismiss are subject to limited inquiry, focusing not on 'whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims.'" *Bolduc*, 2002 U.S. Dist. Lexis 13830 at *3 (quoting *Scheuer v. Rhodes*, 416 U.S. 232, 236 (1974)).

This Court recently observed that in cases like this "where the proof is largely in the hands of the [defendant], dismissals prior to giving the plaintiff ample opportunity for discovery should be granted sparingly." *Hewlett-Packard Co. v. Boston Sci. Corp.*, 77 F. Supp. 2d 189,

195 (D. Mass. 1999). *See also United States ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d 39, 47 (D. Mass. 2001) (strict pleading requirements are relaxed where facts underlying the fraud are particularly within the defendant's control) (Saris, J.).

B. Defendants' 54 Exhibits Only Raise Disputed Fact Issues

Apparently not content to rest their motion on the allegations of the Complaint as required by Rule 12(b)(6), Defendants submit 54 exhibits comprising hundreds of pages of extraneous material in an effort to recast Plaintiffs' allegations to their satisfaction. However, "any consideration of documents not attached to the complaint, or not expressly incorporated therein, is forbidden, unless the proceeding is properly converted into one for summary judgment under Rule 56." *Watterson v. Paige*, 987 F.2d 1, 3 (1st Cir. 1993); *see also* Fed. R. Civ. P. 12(b)(6). Although exceptions to this rule exist, there is no exception for documents that either lead to, or themselves contain, conflicting factual inferences, for a court may not take judicial notice of a fact that is "subject to reasonable dispute." *In re Warfarin Sodium Antitrust Litig.*, 214 F.3d 395, 398 (3d Cir. 2000); *see also Roeder v. Alpha Indus., Inc.*, 814 F.2d 22, 25 (1st Cir. 1987) ("In ruling on a motion to dismiss, . . . a court should not decide questions of fact.").[8]

Defendants' effort to re-write the MCC through the introduction of 54 exhibits simply highlights the fact that factual conflicts and inferences abound. Some examples:

- Defendants construe their exhibits as showing that the federal government has "known for many years that the published AWPs frequently are much higher than the prices at which providers actually purchase drugs." Defs.' Mem. at 3. Even if this assertion is true, not ***one*** of Defendants' exhibits "proves" that the federal government, let alone Plaintiffs here, were aware of Defendants fraudulent AWP scheming. Indeed, as the Complaint illustrates, the federal government ***only recently*** investigated the drug manufacturers and expressed both ***surprise and outrage*** at the AWP fraud, *see, e.g.*, ¶¶ 89-91, disproving Defendants' suggestion

[8] Indeed, many of the proffered exhibits can hardly meet Rule 201's requirement of being a "fact" that "is either (1) generally known within the territorial jurisdiction of the trial court or (2) capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b). Based upon the holding in *Watterson, supra*, and the requirements of Rule 201, this Court has authority to strike Defendants' exhibits.

that Congress has for many years condoned their gaming and manipulation of AWPs, or at least creating a factual issue.

- Defendants quote CMS Administrator Thomas Scully's March 14, 2002 testimony advocating reform of the system. Defs.' Mem. at 14. However, the quotation is selective, as Defendants fail to note other portions of Mr. Scully's testimony where he states that "***AWP is intended to represent the average price at which wholesalers sell drugs to their customers, which include pharmacies and physicians***." Defendants' Exhibit 27 at 5 (emphasis added).

- Defendants cite to a November 6, 1992 report for the proposition that "AWP is not intended to reflect physician's costs." Def. Mem. at 9. The citation is misleading. In fact, HCFA specifically disagreed with many of the findings in this report, concluding with the observation that "[w]e are not prepared to agree that HCFA should reimburse physicians at the lowest price available in the marketplace without evidence that a substantial number of physicians have access to that price." *Id.* at 3.

Moreover, Plaintiffs vigorously dispute Defendants' interpretation of Congress' alleged refusal to take additional action as an acquiescence to allow Defendants to set the AWP at any level they chose as part of a fraudulent scheme to market its drugs. An alternative, and far more likely, interpretation of Congressional intent is that Congress could not determine whether the AWP was inflated for all drugs or by how much, and requested regulators to undertake more complete study of the matter.

These are just several examples highlighting that Defendants' extraneous exhibits merely raise factual conflicts that cannot be resolved at this time.[9] The controlling allegations of the Complaint contradict Defendants' claims and establish that neither Plaintiffs nor the Class knew that the published AWPs were deliberately inflated in order to drive market share and prescription behavior.

[9] The factual conflicts raised by these exhibits are further illustrated in the chart that appears as Exhibit 1 attached to the Affidavit of Thomas M. Sobol Regarding Plaintiffs' Consolidated Memorandum in Opposition to Defendants' Motion to Dismiss submitted herewith.

V. THIS CASE DOES NOT REQUIRE THE COURT TO REJECT OR REWRITE MEDICARE POLICY

Defendants argue that the MCC "depend[s] entirely" on a specific interpretation of the term average wholesale price as "the actual cost at which providers acquire drugs, or some close variant of that." Defs.' Mem. 17. They claim that this interpretation would "override years of federal policy-making" and "trump the current, ongoing political debate" on Medicare drug pricing. Remarkably, Defendants argue that no court has jurisdiction to interpret the requirements of Medicare drug pricing because no definitions, no limitations and no interpretable statute or regulations exist on how much Defendants may charge the government or Medicare beneficiaries. Equally remarkable, Defendants argue that the absence of interpretable federal statutes or regulations precludes this Court from adjudicating claims for relief for fraudulent reimbursement disclosures entirely in the private sector. These arguments lack merit and completely ignore the claim at issue – that Defendants have published false AWPs as part of a scheme to bilk those paying for their drugs.

A. Plaintiffs Do Not Allege, And Need Not Establish, That AWP Approximates Actual Acquisition Cost: Alleging That Defendants Reported Fictitious AWPs Suffices

Defendants' characterizations of the MCC are simply wrong. Putting aside for the moment the fact that the Complaint challenges unlawful activity striking far beyond co-payments in the Medicare realm, even those aspects of the case related to Medicare do not seek to "override years of federal policy-making." Among other things, the MCC alleges Defendants' purposeful manipulation of stated average wholesale prices to increase profits to providers, PBMs and others in the drug distribution chain. The alleged wrongful conduct violates federal and state law, and Defendants are currently the subject of widespread investigation for these unlawful acts. The allegations in the Complaint are not sanctioned by Congress. If they were, neither Bayer nor TAP would have settled claims brought by the government challenging the practice. Further, there is no support for the association that disguised, unlawful kickbacks, rebates or other secret payments designed to manipulate provider or PBM behavior, as alleged in the MCC, would be conduct condoned by Congress.

Defendants erroneously suggest that "Plaintiffs' entire case is predicated on the basic contention that defendants were legally required to report AWPs at the providers' actual acquisition cost, or something close to that." Defs.' Mem. at 17. To the contrary, and as expressed throughout the Complaint, Plaintiffs' core legal theory, claims and damages focus on Defendants' reporting of ***false and inflated*** AWPs in order to manipulate prescription drug prices. But a few examples include the following:

- [T]he Defendant Drug Manufacturers report to trade publications a drug price – the Average Wholesale Price (or 'AWP') – that is deliberately set far above the prices that their drugs are available in the marketplace. The AWPs for these drugs are deliberately false and fictitious and created solely to cause Plaintiffs and the Class members to overpay for drugs. [¶ 3]

- Defendant[s] often promote their drugs not simply with lower prices, but with reimbursement rates based on a fictitious AWP that allows purchasers and intermediaries (including providers and PBMs) to make inflated profits . . . at the expense of Plaintiffs and the Class. [¶ 6]

- All Defendants actively conceal, and caused others to conceal, information about the true pricing structure for the prescription drugs, including the fact that the AWPs for the drugs are deliberately overstated. [¶ 7]

- The AWPs for the drugs at issue here bore no relationship to the drugs' pricing in the marketplace. They were simply fabricated in furtherance of Defendants' scheme to generate the profit spread to providers, PBMs and others and to increase Defendants' profits at the expense of Plaintiffs and the Class members. [¶ 137]

- Certain drug manufacturers have abused their position of privilege in the United States by reporting falsely inflated drug prices in order to create a de facto improper kickback for their customers. [¶ 153 (quoting Congressman Stark)]

- During the Class Period, [Defendants] deliberately and intentionally published AWPs for Covered Drugs that did not reflect the actual pricing structure of the drugs, but was created solely to cause Plaintiffs and the Class members to overpay for the Covered Drugs. [¶ 159]

By Defendants' deliberate decision to report AWPs to national pharmaceutical industry publications – ***knowing that these published AWPs would form the basis of an industry-wide reimbursement system*** – Defendants were obligated by law to ensure that these pricing benchmarks were ***not*** misleading. It is axiomatic under RICO and other statutes prohibiting misrepresentations that "a party who discloses partial information that may be misleading has a duty to reveal all the material facts he knows to avoid deceiving the other party." *V.H.S. Realty,*

Inc. v. Texaco, Inc., 757 F.2d 411, 414 (1st Cir. 1985) (Mass. unfair and deceptive acts statute); *see also Roeder*, 814 F.2d at 26 (RICO and securities claims); *Logan Equip. Corp. v. Simon Aerials, Inc.*, 736 F. Supp. 1188, 1200 (D. Mass. 1990) (common law misrepresentation claims).

Indeed, in a case involving RICO claims, the First Circuit has specifically held that "[w]here a corporation does make a disclosure – ***whether it be voluntary or required*** – there is a duty to make it complete and accurate." *Roeder*, 814 F.2d at 26 (emphasis added). "'Fragmentary information may be as misleading . . . as active misrepresentation, and half-truths may be as actionable as whole lies . . . ." *V.H.S. Realty*, 757 F.2d at 414-15 (quoting *Kannavos v. Annino*, 356 Mass. 42, 48, 247 N.E. 2d 708 (1969)). Thus, if a drug manufacturer "chooses to reveal relevant, material information even though it had no duty to do so, it must disclose the whole truth." *Roeder*, 814 F.2d at 26 (quoting *Grossman v. Waste Mgmt., Inc.*, 589 F. Supp. 395, 409 (N.D. Ill. 1984)).[10]

Plaintiffs' Complaint adequately alleges that Defendants engaged in a sophisticated and deliberately concealed scheme to artificially inflate AWPs. *See Roeder*, 814 F.2d at 26; *In re Number Nine Visual Tech.*, 51 F. Supp. 2d at 18. No measure of obfuscation by Defendants can re-write Plaintiffs' Complaint.

B. The Term "AWP" Is Capable of Definition

In 1997 Congress amended the Medicare statute to provide that the reimbursement "amount payable for [a coverable] drug or biological is equal to 95 percent of the average wholesale price." 42 U.S.C. § 1395u(o)(1). This statutory requirement – a statutory requirement which is germane to this case to the extent the claims are based on Medicare co-payments from 1998 forward – presents a routine matter of statutory construction.[11]

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[10] *See also Turner v. Johnson & Johnson*, 809 F.2d 90, 100 (1st Cir. 1986) (finding that "an incomplete or partial statement may be the basis for fraud when only full disclosure would avoid deception . . . ."); *Augat, Inc. v. Collier*, 1996 U.S. Dist. Lexis 2702 at *47 (D. Mass., Jan. 22, 1996) (noting that disclosure of partial information may be fraudulent); *Union Pac. Res. Group, Inc. v. Rhone-Poulenc, Inc.*, 247 F.3d 574, 586 (5th Cir. 2001) (finding disclosure of "some but less than all material facts" may be actionable where "partial disclosure convey[s] a false impression.").

[11] After passage of § 1395u(o), HHS promulgated regulations to explain implementation of this statute, stating that the methodology for payment is "the lower of the actual charge on the Medicare claim for benefits for 95

It is a well-established canon of statutory construction that by "using terms undefined in the statute, Congress intended the words to have their natural, ordinary and familiar meaning." *United States v. 525 Co.*, 342 F.2d 759, 761 (5thCir. 1965) (citing *First Nat'l Bank of Cincinnati v. Flershem*, 290 U.S. 504 (1934)). The word "average" can mean "a mean proportion, medial sum or quantity, made out of unequal sums or quantities," BLACK'S LAW DICTIONARY at 135 (6th ed) (hereinafter "Black's"), or simply "typical" or "usual." AMERICAN HERITAGE DICTIONARY at 144 (2d ed. 1991). Black's defines "wholesale price" as "that which retailer pays in expectation of obtaining higher price by way of profit from resale to ultimate consumer." *Id.* at 1597. Read together and applied in this context, the natural, ordinary and familiar meaning of "average wholesale price" is a mean proportion or medial, or a typical or usual, amount that intermediaries pay before resale to the ultimate consumers.

While one need not go beyond the plain language of the statute, the administrator of the Centers for Medicare & Medicaid Services nonetheless provides a further answer: "the AWP is intended to represent the average price at which wholesalers sell drugs to their customers, which include physicians and pharmacies." *See* Defendants' Exhibit 27 at 5.[12]

Normal statutory construction of the term AWP cannot result in the conclusion Defendants' strive for: that AWP can mean phony prices that are much higher than those paid by any commercial entity. Logic and sensible statutory construction commands that AWP be a real average of real prices.

Conspicuously absent from Defendants' papers is their own definition or interpretation of AWP. Defendants make no attempt to educate Plaintiffs or this Court on how they determine

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percent of the *national* average wholesale price of the drug or biological." 42 C.F.R. § 405.517(b) (emphasis supplied).

[12] *Testimony of Thomas A. Scully, Administrator of Centers for Medicare & Medicaid Services, on Reimbursement & Access to Prescription Drugs under Medicare Part B, Senate Finance Committee, Subcommittee on Health* at 5. This testimony appears in Defendants' Appendix of Exhibits at Exhibit 27. Again, Plaintiffs believe that the Court should not consider Defendants' exhibits in deciding the instant motion. But if the Court decides to review such exhibits, the Court should well consider Administrator Sculley's definition of AWP. *Harrington v. Chao*, 280 F.3d 50, 59 (1st Cir., 2000). (Judicial deference to agency interpretations is premised in part on the notion that agencies have greater expertise in their area of specialty than do courts) (citing *Chevron, U.S.A. Inc. v. National Resources Defense Council, Inc.*, 467 U.S. 837, 836-66 (1984).

AWPs – a strange omission considering only they are privy to the process. Instead, Defendants offer volumes of "legislative history" in an effort to prove what AWP is not. Defendants argue that AWP should bear no relationship to their actual acquisition costs and go so far as to suggest that this Court "cannot find that AWP means ***anything close*** to provider acquisition cost," Defs.' Mem. at 27 (emphasis added), yet Defendants provide no legal authority for their proposition and it is contrary to common sense and statutory construction.

C. The Political Question Doctrine Does Not Apply In This Case

Invoking the political question doctrine, Defendants contend that because Congress has decided "to leave the AWP-based reimbursement system in place," this Court "cannot grant relief on any of the Plaintiffs' claims unless it rewrites a reimbursement rule. . . ." Defs.' Mem. at 19-21. These assertions are without merit.

1. The Political Question Doctrine Is Narrowly Proscribed And Does Not Apply Here

The political question doctrine prevents a federal court with jurisdiction over a dispute from adjudicating questions that should be addressed by the political branches of government. *Baker v. Carr*, 369 U.S. 186, 210 (1962) (holding justiciable an equal protection claim based on state legislative appointment that allowed substantial disparities in number of voters represented by each state representative). To determine whether a matter raises non-justiciable political questions, courts examine whether any of the following factors exist: (i) a demonstrable constitutional commitment of the issue to a coordinate political department; (ii) the lack of judicially discoverable and manageable standards for resolving it; (iii) the impossibility of making a decision without first making a policy determination of the type clearly outside judicial discretion; (iv) the court's inability to resolve the issue without expressing lack of respect to the coordinate branches of government; (v) an unusual need for unquestioning adherence to a political decision already made; or (vi) the potential for embarrassment from multifarious pronouncements by various departments on one question. *Id.* at 217. The doctrine must be cautiously invoked, and the mere fact that a case touches on the political process does not

necessarily create a political question beyond court jurisdiction. *See Nixon v. Herndon*, 273 U.S. 536, 540 (1927); *Can v. United States*, 14 F.3d 160, 163 (2d Cir. 1994).

None of the *Baker* factors apply to the claims here. Plaintiffs' case does not in any way challenge Medicare's use of AWP as a basis for reimbursement, and the Court will not be called upon to rewrite reimbursement rules.[13] The only challenged conduct is Defendants' gaming of that reimbursement system through the fraudulent reporting of AWPs. ***Even though the Medicare reimbursement system is based on the use of AWPs, this reimbursement structure does not provide Defendants with a free license to fraudulently game the system by deliberately publishing inflated and misleading price data that directly results in excessive payments by Plaintiffs and the Class. Such conduct is unlawful and may be remedied by a court employing well-established federal and state law.*** Plaintiffs' dispute is with Defendants – not the Medicare reimbursement system or government officials. Defendants "have abused their position of privilege in the United States by reporting falsely inflated drug prices[.]" ¶ 153. Simply stated, Plaintiffs' claims arise from Defendants' manipulation, inflation, and misuse of AWP – not because Medicare's drug reimbursement system ***provided them the opportunity*** to commit fraud.[14] Claims of this sort are uniquely appropriate for judicial resolution.

2. No Persuasive "Political Question" Case Law Is Cited

Defendants' political question argument rests almost entirely on *Stephenson v. Shalala*, 87 F.3rd 350 (9th Cir. 1996), but this reliance is completely misplaced. *Stephenson* is not even a political question case – it cites no political question case law and it does not invoke the concept or words "political question" in any way. Indeed, *Stephenson* is an example of precisely what

[13] Notably, the political question doctrine did not impede civil and criminal settlements between certain Defendants and government officials (such as Abbott, Bayer and Pfizer) relative to their role in the manipulation, inflation and misuse of AWP.

[14] Moreover, there is no support for Defendants' suggestion that – by interpreting the plain meaning of AWP in the Medicare regulations, 42 C.F.R. § 405.517 – this Court would somehow be impermissibly treading on the province of Congress. Statutory interpretation is routinely performed by courts, and the fact that a term is undefined in a statute does not render it void of meaning. To the contrary, it is a well-established canon of statutory construction that by using terms undefined in the statute, Congress intended the words to have their natural, ordinary and familiar meaning, *see, e.g.*, *First Nat'l Bank v. Flershem*, 290 U.S. 504 (1934), and that courts are perfectly capable of discerning that meaning. Indeed, courts do this throughout the country every day.

the Defendants here seek to avoid, a case of judicial construction and interpretation of federal statutes and regulations.

Moreover, the *Stephenson* court's interpretation of the Medicare laws is not apposite to this case. There, the plaintiffs challenged HHS' interpretation of a Medicare law that permitted hospitals to charge "customary" rates rather than, as the plaintiffs there would have it, "reasonable" rates which HHS would affix through a national rate and specified cap structure. In *Stephenson*, because Congress and HHS had long adopted and maintained the "customary" rate regime (and had expressly decided not to require HHS to establish a national rate structure), the court was disinclined to interpret the Medicare statute as requiring anything more. *Stephenson*, 87 F.3rd at 355-56. This case thus bears no real resemblance to *Stephenson*. This case does not seek to revamp the AWP system; it seeks to enforce existing law and applicable agency interpretation of that law.[15]

One federal court has already recognized that an attack on fraudulently overstating AWPs does not equate to an attack on the Medicare reimbursement system itself. In *State of Minnesota v. Pharmacia Corporation*, C.A. No. 02-1779 (D. Minn., Sept. 27, 2002), Minnesota claimed that Pharmacia "unlawfully inflated the average wholesale price ('AWP') of certain of its chemotherapy drugs." Report and Recommendation, Chief U.S. Magistrate Judge Jonathan

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[15] Defendants' two political question cases are of no help to them. In *Japan Whaling Ass'n v. American Cetacean Soc'y*, 478 U.S. 221, 229-30 (1986), the Court rejected an effort to bar conservation groups from seeking a writ of mandamus to compel the U.S. Secretary of Commerce to certify Japanese whaling activities as violative under the Pelly and Packwood-Magnuson Amendments. Even though the issue raised highly charged foreign relations policy questions, the Supreme Court *rejected* the argument that the case was beyond judicial resolution due to the political question doctrine, stating that "not every matter touching on politics is a political question," and that "it goes without saying that interpreting congressional legislation is a recurring and accepted task for the federal courts." *Id.* at 230.

Beacon Prod. Corp. v. Reagan, 633 F. Supp. 1191 (D. Mass. 1986), *aff'd*, 814 F.2d 1 (1st Cir. 1987), the other political question case cited by Defendants, also demonstrates the narrow reach of the political question doctrine. In *Beacon Prod.*, the plaintiffs sued the President of the United States claiming he had exceeded his statutory and constitutional authority by imposing an embargo on trade with the Republic of Nicaragua. The Plaintiffs also claimed that the Department of State had acted unconstitutionally by notifying Nicaragua of a treaty termination without congressional approval. The *Beacon* court addressed two questions. As to the question of whether Nicaragua posed an "unusual or extraordinary threat" to trigger certain actions, such a determination would, of course, be a political one. However, the question of whether the President had exercised powers pursuant to an unconstitutional statute, a claim that would not require the Court to second-guess the President's foreign policy judgment, was determined not to be a political one. The Court rejected the political question doctrine as a bar to this claim and addressed the plaintiffs' claims on the merits. *Id.* at 1194-96.

Lebedoff, September 27, 2002 ("Report") at 1-2.[16] Bringing claims for consumer fraud, fraud on senior citizens and handicapped persons, Medicaid fraud, common law fraud, false advertising, and unjust enrichment, Minnesota alleged that "[Pharmacia's] fraud has caused the Minnesota Medicaid program and individual Minnesota Medicare beneficiaries to pay 'grossly excessive' prices for [Pharmacia's] drugs." *Id.* at 2. In recommending remand and rejecting Defendants' assertions of federal question jurisdiction, Chief Magistrate Judge Lebedoff wrote that "[Minnesota] is not attacking the federal program. [Minnesota] does not even challenge the use of AWP as the basis for drug pricing, reimbursement, and co-pay schemes." *Id.* at 9. His Report emphasized that Pharmacia had mischaracterized Minnesota's claims:

> [Minnesota] is not seeking to have AWP reporting requirements changed. [Minnesota] is merely asking that [Pharmacia] ***be required to report honestly*** so as to not violate Minnesota law. . . . The Hennepin County District Court ***will not be called upon to evaluate the validity or sufficiency of federal Medicare or Medicaid law***. [Minnesota] is not attacking Medicare's and Medicaid's policies of using AWP as a basis for reimbursement. Rather, [Minnesota] ***is only attacking [Pharmacia's] alleged untruthful reporting of AWP***. Providing this relief would not prohibit Medicare from using AWP as its basis for reimbursement.

Id. at 11-12 (citations omitted) (emphasis added).

Similarly, in the present action, Plaintiffs do not take issue with Medicare's drug pricing, reimbursement or co-pay schemes, and they do not seek to have AWP reporting requirements changed. As the Magistrate found in *Pharmacia*, this Court will not be called upon to evaluate the validity or sufficiency of Medicare law.[17]

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[16] The Report is attached to the Affidavit of Thomas M. Sobol as Exhibit 2. This opinion was not cited by Defendants though some were parties to the litigation. An objection to the report was also filed by Defendants and the Plaintiffs are not aware of any further action taken with respect to the Report.

[17] Defendants make a passing reference to the "[p]rudential limitations on the exercise of Article III jurisdiction" with a citation to *Warth v. Seldin*, 422 U.S. 490, 499-500 (1975). Defs.' Mem. 19. It is unclear from this passing reference whether Defendants intend to argue some or all claims should be dismissed on the strength of *Warth*; if they do, this oblique reference may not rise to a level of argument that warrants court review. In any event, the *Warth* Court addressed issues of standing and did not, as the Defendants seem to suggest, articulate a broad "doctrine of prudential abstention."

VI. COUNTS I-IV OF THE COMPLAINT PROPERLY PLEAD RICO VIOLATIONS

A. An Overview Of Plaintiffs' Civil RICO Claims And Their Necessary Elements

Counts I, II, III and IV assert four separate substantive claims against Defendants for violations of Section 1962(c) of RICO. Each count properly alleges all elements required by the statute, First Circuit precedent, Rule 8(a) and, where applicable, Rule 9(b). The scope of each civil RICO claim is summarized as follows:

- Counts I (¶¶ 343-369) and II (¶¶ 370-396) assert claims on behalf of Class 1 members against Defendants for unlawful conduct associated with Medicare Part B Covered Drugs.
- Counts III (¶¶ 397-423) and IV (¶¶ 424-450) are brought on behalf of Class 2 members against Defendants (excluding the Boehringer Group, Braun, Dey, Fujisawa and Watson Defendants) for unlawful conduct associated with brand name prescription drugs.

Section 1962(c) of RICO makes it "unlawful for any person[18] employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity. . . ." 18 U.S.C. § 1962(c). Thus, plaintiffs or the government must prove the same elements: (i) an enterprise existed; (ii) the enterprise participated in, or its activities affected, interstate commerce; (iii) the defendant was employed by or was associated with the enterprise; (iv) the defendant conducted or participated in the conduct of the enterprise; (v) through a pattern of racketeering activity. *United States v. Marino*, 277 F.3d 11, 33 (1st Cir. 2002) (citing *United States v. Shifman*, 124 F.3d 31, 35 (1st Cir. 1997)); *see also North Bridge Assocs., Inc. v. Boldt*, 274 F.3d 38, 42 (1st Cir. 2001).[19]

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[18] Paragraphs 345 (Count I), 372-373 (Count II), 399-400 (Count III) and 426-427 (Count IV) properly allege that each of the Plaintiffs and each Defendant is a "person." *See* 18 U.S.C. § 1961(3) ("'person' includes any individual or entity capable of holding a legal or beneficial interest in property"). Defendants apparently do not contest these allegations.

[19] In their brief, Defendants inexplicably ignore First Circuit ***criminal*** RICO precedents demonstrating that Plaintiffs' ***civil*** RICO claims are properly pled. The First Circuit has repeatedly stated that "it is appropriate to rely on civil RICO precedent when analyzing criminal RICO liability. The standard is the same for both criminal and civil RICO violations." *Marino*, 277 F.3d at 33 n.6 (quoting *Shifman*, 124 F.3d at 35 n.1). Of course, civil RICO claims must only be proved "by a preponderance of the evidence." *Aetna Cas. & Sur. Co. v. P & B Autobody*, 43 F.3d 1546, 1560 (1st Cir. 1994) (citing *Combustion Eng'g, Inc. v. Miller Hyrro Group*, 13 F.3d 437, 446 (1st Cir. 1993)).

The following chart summarizes the requisite elements of Plaintiffs' civil RICO claims and where each element is alleged:

Elements of Civil RICO Claims:	**Count I** (¶¶ 343-369)	**Count II** (¶¶ 370-396)	**Count III** (¶¶ 397-423)	**Count IV** (¶¶ 424-450)
"Persons"	¶ 345	¶¶ 372-373	¶¶ 399-400	¶¶ 426-427
"Enterprise(s)"	¶¶ 346-350 (AWP Enterprises); ¶ 351 (Payor Enterprises)	¶¶ 375-377 (Publisher Enterprises); ¶ 378 (Payor Enterprises)	¶¶ 402-404 (Publisher Enterprises); ¶ 405 (Payor Enterprises)	¶¶ 429-431 (PBM Enterprises); ¶ 432 (Payor Enterprises)
"Racketeering Activity"	¶¶ 352-356 (Mail/Wire Fraud)	¶¶ 379-383 (Mail/Wire Fraud)	¶¶ 406-410 (Mail/Wire Fraud)	¶¶ 433-437 (Mail Fraud/Wire Fraud)
"Pattern of Racketeering Activity"	¶¶ 360-364	¶¶ 387-391	¶¶ 414-418	¶¶ 441-445
"Conduct" of Enterprise(s)	¶¶ 345, 357-359	¶¶ 374, 384-386	¶¶ 401, 411-413	¶¶ 428, 438-440
"Defendants' Motive"	¶¶ 365-366	¶¶ 392-393	¶¶ 419-420	¶¶ 446-447
"Plaintiffs' Injury"	¶¶ 367-369	¶¶ 394-396	¶¶ 421-423	¶¶ 448-450

B. The Complaint Properly Identifies The RICO Enterprises

1. The RICO "Enterprise" Concept

"Enterprise" is defined broadly to include "any individual partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity." 18 U.S.C. § 1961(4). Thus, to satisfy the "enterprise" element, Plaintiffs must allege "either the existence of a legal entity, such as a corporation, or that a group of individuals were associated-in-fact." *Aetna*, 43 F.3d at 1557. An association-in-fact enterprise is an "ongoing organization," whether "formal or informal," with members "function as a continuing unit," which is "separate and apart from the pattern of activity in which it engages." *United States v. Turkette*, 452 U.S. 576, 583 (1981). An association-in-fact RICO

enterprise may consist of "two or more legal entities," or "two legal entities and two individuals." *United States v. London*, 66 F.3d 1227, 1243 (1st Cir. 1995).

2. The "AWP Enterprises"

In Count I, Plaintiffs allege that each Defendant formed an association-in-fact enterprise with the medical providers who prescribed Covered Drugs for which that Defendant reported an AWP (the "AWP Enterprises"). ¶ 346. For example, the "Abbott Provider Enterprise" is described as an "association-in-fact consisting of the various and independent medical providers who prescribed Covered Drugs for which Abbott reported an AWP, and Defendant Abbott, including its directors, employees and agents." ¶ 350(a).[20] Plaintiffs allege that each of the "AWP Enterprises" is "an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purpose of selling, purchasing, prescribing, and administering Covered Drugs to individual Plaintiffs and Class 1 members, and to participants in those Plaintiffs and Class 1 members that comprise health and welfare plans, and deriving profits from these activities." ¶ 350(a)-(u).

Paragraphs 346-349 and 350(a)-(u) describe in requisite detail the "ongoing organization" of each alleged association-in-fact enterprise, and those paragraphs also explain how each association-in-fact "function[ed] as a continuing unit." *Aetna*, 43 F.3d at 1557 (quoting *Turkette*, 452 U.S. at 583). Nothing more is required. *See id.*; *see also Doyle v. Hasbro, Inc.*, 103 F.3d 186, 19 (1st Cir. 1996)). Yet, ignoring First Circuit precedent, Defendants raise a variety of pleading challenges to the AWP Enterprises. Each challenge fails.

a. The First Circuit expressly authorizes alternative enterprises

Defendants complain that the Complaint identifies too many RICO "enterprises," and they decry Plaintiffs' use of "alternative" allegations. *See* Defs.' Mem. at 25-26. However, in *Aetna*, 43 F.3d at 1553-57, the First Circuit upheld a jury verdict for the plaintiff insurer in a civil RICO action arising from the submission of false auto insurance claims in which Aetna alleged

[20] The respective AWP Enterprises for the other Defendants are defined in ¶¶ 350(b)-(u).

in the alternative a variety of different enterprises in which defendants participated. Similarly, in *Liberty Mut. Ins. Co. v. Diamante*, 138 F. Supp. 2d 47 (D. Mass. 2001), where the plaintiff insurer asserted civil RICO claims against 20 individual and corporate defendants who were alleged to have submitted phony medical insurance claims, Chief Magistrate Judge Collings upheld RICO claims involving a half-dozen alternative enterprises. *Id.* at 55-61.[21]

b. The First Circuit has rejected an "ascertainable structure" enterprise requirement

Defendants assert – without citing any precedent – that "an association in fact enterprise must be a tightly organized unit with a defined hierarchy in which all members work in concert to achieve a common objective." Defs.' Mem. at 27. Defendants' position, however, is untenable under First Circuit RICO precedent. In *United States v. Patrick*, 248 F.3d 11 (1st Cir. 2001), the defendant "street gang" members appealed their criminal RICO convictions, contending that Judge Keeton erred in refusing to instruct the jury that "at a minimum, the enterprise must exhibit ***some sort of structure for the making of decisions, whether it be hierarchical or consensual***." *Id.* at 18 (emphasis added). The RICO indictment charged that defendants were associated in fact to form a "street gang" that conducted drug transactions. *Id.* at 17. Affirming their RICO convictions, the First Circuit rejected defendants' contention that it should adopt an "ascertainable structure" definition of a RICO "enterprise," observing that the district court had properly derived the jury instruction defining "enterprise" from the Supreme Court's decision in *Turkette*, and that "no more was needed to define the term 'enterprise' for the jury." *Id.* at 18. "Since Congress intended the term 'enterprise' to include both legal and criminal enterprises, . . . and because the latter may not observe the niceties of legitimate organizational structures, we refuse to import an 'ascertainable structure' requirement into jury instructions."[22] *Id.* at 19.

[21] In *Liberty Mutual*, Judge Lindsay accepted the magistrate judge's recommendations concerning defendants' motions to dismiss the civil RICO claims.

[22] Indeed, in previous RICO cases the First Circuit had never adopted the "ascertainable structure" definition for association-in-fact enterprises. *Patrick*, 248 F.3d at 18 (citing *United States v. London*, 66 F.3d at 1244 (association-in-fact enterprise consisted of corporation and sole proprietorship engaged in bookmaking and extortion), and *United States v. Owens*, 167 F.3d 739, 752 n.6 (1st Cir. 1999) (large-scale cocaine distribution enterprise)).

In another recent case, *In re Managed Care Litigation*, 185 F. Supp. 2d 1310 (S.D. Fla. 2002), the plaintiffs, who were insureds or subscribers to various health care insurance plans, brought a civil RICO action against managed care insurance companies alleging misrepresentations relating to various aspects of their health insurance coverage. Plaintiffs alleged that each of the defendant insurance companies associated with a RICO enterprise consisting of (i) the insurance company; (ii) the insurance company's health plans; and (iii) the primary physicians, medical specialists, medical laboratories, hospitals, outpatient centers, pharmacies, and home health agencies that contract with the defendant insurance company. *Id.* at 1322. The district court upheld the RICO enterprise allegations, observing that the Eleventh Circuit (like the First Circuit) has "no strict 'structure' requirement." *Id.* at 1323 (citing, *inter alia*, *Avirgan v. Hull*, 932 F.2d 1572, 1578 (11th Cir. 1991) ("[A] RICO enterprise may be an 'amoeba-like' structure of a loose informal association.")). The defendants argued that "a RICO enterprise requires a structure beyond that commonly found in ongoing contractual relationships." *Id.* But even so, plaintiffs' allegations more than sufficed:

> Even if the Court adopted this heightened standard, each National Enterprise pled by the Plaintiffs would likely prevail. All of the relevant published cases cited by the Defendants describe a putative enterprise consisting of either a random collection of contracting entities, independent actors committing criminal acts within a particular industry, or a manufacturer selling a product through independent distributors. The Plaintiffs in the present case have not alleged a series of random contractual exchanges, but a network of physicians, hospitals, pharmacies and health care professionals through which the Defendants deliver health care to the subscribers.

185 F. Supp. 2d at 1323-24 (footnote omitted). The specific allegations of Paragraphs 346-350 of the Complaint demonstrate that the same conclusion should apply in this case. *See also Pharmacare v. Caremark*, 965 F. Supp. 1411, 1421-23 (D. Haw. 1996) (in civil RICO action brought by competitors of corporation providing alternate site infusion therapy, plaintiffs properly defined "enterprise" as association-in-fact between defendant corporate entities "and the

doctors who received bribes" from defendants so that they would prescribe defendants' products rather than plaintiffs' competing products).[23]

c. Plaintiffs allege that the members of each enterprise had a common purpose

Defendants contend that the members of the "AWP Enterprises" do not have a "common purpose merely by participating in a particular industry or through a connection to a particular party or defendant." Defs.' Mem. at 29. However, Plaintiffs allege that Defendants and the providers had a "common purpose" to ***make money*** by engaging in the "AWP Scheme" relating to the Covered Drugs. ¶¶ 349-50. Under the First Circuit's decision in *United States v. London*, these allegations suffice. In *London*, the criminal RICO defendant operated a bar (Heller's) and a check-cashing service (M & L). 66 F.3d at 1230. The alleged RICO enterprise was an association-in-fact between Heller's (a corporation) and M & L (a sole proprietorship). *Id.* at 1243. The government charged that London conducted the affairs of the enterprise through a pattern of racketeering activity that included illegal bookmaking and extortion. *Id.* at 1230. Notwithstanding the seemingly unrelated nature of the bar and check-cashing businesses, in affirming London's RICO conviction the First Circuit stated that "[t]he jury could have found that there was a common or shared purpose animating both the enterprise and London: doing commerce with (and thereby profiting from) bookmakers engaged in illegal gambling." *Id.* at 1244; *see also United States v. Cianci*, 210 F. Supp. 2d 71, 74-75 (D.R.I. 2002) (a legal entity need not share the criminal purposes of the individuals controlling it in order to be part of an association-in-fact enterprise).[24]

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[23] The district court in *Pharmacare* reached this conclusion even though the Ninth Circuit requires that a RICO enterprise have an "ascertainable structure." 965 F. Supp. at 1422. Chief Judge Kay wrote that "this requirement may be fulfilled by the simple inclusion of a corporation as a participant in the enterprise." 965 F. Supp. at 1423; *see also Webster v. Omnitron Int'l*, 79 F.3d 776, 786 (9th Cir. 1996). Defendants cannot dispute that Plaintiffs' Complaint alleges that corporate entities are alleged to be participants in the "AWP Enterprises." ¶ 350(a)-(u).

[24] *Cianci* arose from the criminal RICO prosecution of the mayor of Providence, Rhode Island, a city official and the operator of a private business. The alleged enterprise was an association-in-fact consisting of the individual defendants, Mayor Cianci's political fundraising organization, and various city departments and agencies that defendants used to award contracts and jobs in exchange for bribes and political contributions. *Id.* at 73. Chief Judge Torres refused to dismiss the RICO indictment, even though defendants argued that the alleged association-in-fact enterprise did not have a "common purpose" because "the City and its departments were legitimate entities that did not subscribe to the defendants' alleged criminal objectives." *Id.*

Defendants' reliance upon *Blue Cross v. SmithKline Beecham Clinical Labs., Inc.*, 62 F. Supp. 2d 544 (D. Conn. 1998), is misplaced. Defs.' Mem. at 29. In that case, the plaintiff insurance companies and patients who paid for clinical laboratory tests conducted by SmithKline asserted civil RICO claims, contending that SmithKline had engaged in fraudulent billing practices. *Id.* at 547, 549. Plaintiffs contended that the RICO enterprise was a nationwide "billing network" consisting of SmithKline, its personnel and the hospitals, physicians, physician practice groups, and laboratories to which the fraudulent bills had been sent. *Id.* at 550. The district court found that the physicians, hospitals and laboratories that had allegedly been fooled by SmithKline's fraudulent billing scheme did not share a "common purpose" with the defendants. *Id.* at 552. The court wrote that plaintiffs' complaint was "devoid of any specific allegation that any physician, hospital, or laboratory shared [defendants'] alleged common purpose to defraud public and private health care payers." *Id.* at 553. Indeed, the plaintiffs in that case alleged that defendants' "scheme exploited the trust of both patients and payers in the physicians, as well as the trust of the physicians in [defendants]." *Id.* at 552.

In contrast, in this case Plaintiffs specifically allege that the medical providers who prescribed Covered Drugs[25] were willing, "integral participants" in the AWP Scheme. "Indeed, the providers were the parties who actually sought reimbursement from Plaintiffs and members of Class 1." ¶ 347. The providers were "knowing and willing" participants in the AWP Scheme, ¶ 348, and they shared Defendants' commitment to the scheme in the various ways detailed in ¶ 349(a)-(e). Thus, unlike the association-in-fact enterprise at issue in *SmithKline Beecham*, the members of the "AWP Enterprises" here clearly shared a "common purpose."

3. The Publisher Enterprises

Counts II and III allege the existence of "Publisher Enterprises," namely, associations-in-fact of Defendants and the publishers that reported AWPs for Covered Drugs. Like the "AWP

[25] A "Covered Drug" is a drug that is covered by Medicare Part B and are primarily limited to injectables administered directly by a doctor, certain oral anti-cancer drugs, and drugs furnished under a durable medical equipment benefit. Approximately 450 drugs are covered by Medicare Part B.

Enterprises," the "Publisher Enterprises" are described in detail in ¶¶ 375, 376, 377(a)-(u), 402-403, and 404(a)-(p) of the Complaint.

Challenging the "Publisher Enterprises," Defendants contend that an enterprise cannot consist of "two separate entities engaged in a common business venture." Defs.' Mem. at 29. In *London*, the First Circuit explicitly rejected Defendants' contention that two or more "legal entities" cannot form an association-in-fact enterprise. As Senior Judge Bownes noted, such a restrictive reading of RICO's "enterprise" element "would lead to the bizarre result that only criminals who failed to form corporate shells to aid their illicit schemes could be reached by RICO." *Id.* at 1244. Moreover, notwithstanding Defendants' assertions, RICO enterprises are frequently based on common business ventures. *See, e.g., River City Markets, Inc. v. Fleming Foods West, Inc.*, 960 F.2d 1458, 1462 (9th Cir. 1992) ("Virtually every business contract can be called an 'association in fact [enterprise].'"); *VNA Plus, Inc. v. Apria Healthcare Group, Inc.*, 29 F. Supp. 2d 1253, 1259 (D. Kan. 1998) (commercial contract can serve as the basis of a RICO enterprise); *Loma Linda Univ. Med. Ctr. v. Farmers Group*, 1995 U.S. Dist. Lexis 9668, at *4 (E.D. Cal. May 15, 1995) (noting that "contractual relationships can establish a RICO enterprise"). Thus, once again, Defendants are wrong.[26]

4. The PBM Enterprises

Count IV, which is asserted against Defendants on behalf of Class 2, alleges the existence of "PBM Enterprises," which are associations-in-fact between Defendants and pharmacy benefit managers ("PBMs") that administered purchases of brand name drugs and billed their members on the basis of the reported AWPs. The PBM Enterprises are identified in ¶¶ 429-430 and 431(a)-(p). For the reasons stated in the preceding sections, and contrary to Defendants'

[26] Defendants rely on a footnote in the First Circuit's decision in *Feinstein v. Resolution Trust Corp.*, 942 F.2d 34 (1st Cir. 1991), which dismissed a civil RICO claim because plaintiffs' complaint merely "made a ritualistic averment, in wholly conclusory terms" that defendants formed an association-in-fact enterprise. *Id.* at 42. Such allegations were insufficient because plaintiffs' complaint "contained no allegations articulating how any of the [defendants] may have comprised part of an 'ongoing organization' or 'functioned as a continuing unit.'" *Id.* (quoting *Turkette*, 452 U.S. at 583). *Feinstein* is readily distinguished from this case by comparing the paltry allegations at issue in that case with the detailed allegations found in ¶¶ 375-377 and 402-404.

assertions, *see* Defs.' Mem. at 30, Plaintiffs adequately allege the existence of the PBM Enterprises.

5. The Third-Party Payor Enterprises

Count I also alleges that each of the Third-Party Payors identified as Plaintiffs in ¶¶ 23-26 of the Complaint constitute separate RICO "enterprises." ¶ 351. These are referred to as the "Third-Party Payor AWP Enterprises" and as "victim enterprises." *Id.* Similar enterprise allegations are made in Counts II (¶ 378), III (¶ 405) and IV (¶ 432). Defendants do not challenge the sufficiency of these allegations, *see* Defs.' Mem. at 30-32, nor could they because it is well settled that a plaintiff itself may be a RICO enterprise. *Aetna*, 43 F.3d at 1558; *Liberty Mutual*, 138 F. Supp. 2d at 58-61; Douglas E. Abrams, THE LAW OF CIVIL RICO § 4.3.1, at 186 (1991).

C. The Complaint Properly Alleges That Defendants "Conducted" The Affairs Of The Third-Party Payor AWP Enterprises

Counts I, II, III and IV allege that Defendants violated § 1962(c) by conducting the affairs of the Third-Party Payor AWP Enterprises through a pattern of racketeering activity. ¶¶ 345, 374, 401, 428. Plaintiffs allege that Defendants and the providers "conducted the affairs of each of the Third-Party Payor AWP Enterprises with which they dealt by reporting fraudulently inflated AWPs for Covered Drugs and by submitting false and misleading invoices to Plaintiffs, thereby inducing Plaintiffs to pay inflated amounts for Covered Drugs." ¶ 359.

Grossly misstating the First Circuit's holding in *Aetna*, 43 F.3d at 1559-60, and inexplicably relegating that controlling precedent to a mere footnote, *see* Defs.' Mem. at 32 n.27, Defendants contend that they did not "conduct" the affairs of the Third-Party Payor AWP Enterprises. *See id.* at 32-33. In *Aetna*, as noted above, the plaintiff insurance company brought a civil RICO action alleging that defendants had participated in the affairs of Aetna (the enterprise) through a pattern of racketeering activity. 43 F.3d at 1558. The defendants were an automobile body shop, the owner and employees of the body shop, and relatives and friends of the owners and employees of the body shop who submitted false claims to Aetna for supposed

repairs done by the body shop on certain vehicles. Also named as defendants were two Aetna appraisers who, *inter alia*, "submitted false appraisals to help [the other defendants] defraud Aetna." *Id.* at 1552.

In evaluating whether the defendants (other than the two Aetna appraisers) participated in the conduct of Aetna's affairs, the court applied the "operation or management" test set forth in *Reves v. Ernst & Young*, 507 U.S. 170 (1993), which requires that defendants take "some part in directing the enterprise's affairs." 43 F.3d at 1559. The First Circuit emphasized that the requisite participation "could be 'indirect' in the sense that persons with no formal position in the enterprise can be held liable." In upholding the plaintiff's enterprise theory, the court explained:

> Appraising allegedly damaged vehicles and investigating, processing, and paying automobile insurance claims are vital parts of Aetna's business. By acting with purpose ***to cause Aetna to make payments*** on false claims, appellants were participating in the "operation" of Aetna. . . . The evidence was sufficient to support a finding that the individual Aetna defendants' activities affected, in a material degree, the direction of Aetna's affairs by employees of Aetna. Appellants' activities ***caused*** Aetna employees having authority to do so to direct that other employees ***make payments Aetna otherwise would not have made***. . . . When viewed in the light most favorable to the plaintiff, in support of the verdict in this case, the evidence supports a finding that appellants caused the Aetna appraisers to approve false claims and conduct their appraisals in a manner contrary to Aetna's business practices and ***caused Aetna to pay out large sums of money on false claims***. The evidence was sufficient to support a finding that appellants exerted control over the enterprise, if not by bribery (the example given by the Court in *Reves*), then at least by other methods of ***inducement***. Since a reasonable jury could find that the appellants exerted some control over Aetna and took part in directing some aspect of the enterprise's affairs, the appellants' actions could be found to have satisfied the "operation or management" test.

Id. at 1559-60 (emphasis added; citations omitted).

Citing *Reves* and *Aetna*, Chief Magistrate Judge Collings of this District refused to dismiss civil RICO claims brought by insurance companies against attorneys (and others) who submitted false claims that the insurers paid, stating that the "operation or management" test for § 1962(c) liability posited by *Reves* "may be met by proof that the defendants participated in the operation of the insurance companies [the RICO enterprises] by acting in such a manner as to

cause them to pay false claims which would not have otherwise been paid were it not for the defendants' acts." *Liberty Mutual*, 138 F. Supp. 2d at 61.

The same is true here. Under First Circuit precedent, Plaintiffs properly allege that Defendants conducted the affairs of the Third-Party Payor AWP Enterprises through a pattern of racketeering activity, in violation of § 1962(c).[27]

D. The Complaint Properly Alleges That Defendants Conducted The Enterprises' Affairs Through A Pattern Of Racketeering Activity

Plaintiffs allege that Defendants conducted the specified RICO enterprises through a "pattern of racketeering activity." ¶¶ 360-364, 387-391, 414-418, 441-445. Defendants concede that Plaintiffs' allegations satisfy the "pattern" element.

E. Plaintiffs Properly Allege Acts Constituting Mail And Wire Fraud

"Racketeering activity" is defined as "any act . . . indictable under" enumerated sections of Title 18 of the U.S. Code, including mail and wire fraud. 18 U.S.C. § 1961(1)(B). The elements of a mail fraud violation "are a scheme to defraud and the use of the mails to execute or further this scheme." *Aetna*, 43 F.3d at 1560; *see also McEvoy Travel*, 904 F.2d at 791 n.8 ("Because the relevant language of the mail and wire fraud statutes is the same, we apply the same analysis to the allegations under both statutes."). Significantly, predicate RICO acts can include aiding and abetting mail or wire fraud. *Id.* at 72 n.6 (citing *Aetna*, 43 F.3d at 1560).

Defendants' acts of mail and wire fraud are alleged in ¶¶ 353-355, 356(a)-(i), 380-382, 383(a)-(h), 414-418 and 441-445. The Complaint is replete with allegations detailing Defendants' AWP Scheme, *see* ¶¶ 132-140, 141-182, and each Defendant's willing participation therein. ¶¶ 184-328. As these detailed allegations make clear, Plaintiffs' allegations of mail and

[27] Contrary to Defendants' assertions, *see* Defs.' Mem. at 31, this Court's decision in *Bowdoin Constr. Corp. v. Rhode Island Hosp. Trust Nat'l Bank, N.A.*, 869 F. Supp. 1004 (D. Mass. 1994), does not compel a different result. In that case, a civil RICO action arising out of the financing of renovations at a resort and conference center, the plaintiff general contractor sued the lenders and lawyers who represented the lenders and the developer. *Id.* at 1006. Although this Court refused to dismiss the § 1962(c) claims against the developer, its executives, and the "lead" lender, *id.* at 1009, it dismissed the contractor's claim against a lawyer who "did [nothing more] than provide legal advice and legal services" to the developer. *Id.* at 1010. The theory of liability in that case was completely different than that upheld by the First Circuit in *Aetna*, 43 F.3d at 1559-60, which was decided six weeks after this Court decided *Bowdoin*.

wire fraud are not limited to Defendants' submission of false and misleading AWPs to "independent publishers" as Defendants contend. *See* Defs.' Mem. at 22. The elements of mail and wire fraud are properly alleged.

Nonetheless, and once again mischaracterizing Plaintiffs' claims, Defendants assert that it is not fraud to report AWPs higher than actual acquisition costs and that, therefore, Plaintiffs have not pled a fraud claim upon which a RICO violation can be based. Defs.' Mem. at 21-22. As discussed in greater detail in Section V.A. *supra*, Plaintiffs claims are ***not*** predicated on a finding that AWP equates to actual acquisition cost. Rather, the fraud challenged here is Defendants' reporting of ***false and inflated*** AWPs in order to manipulate reimbursements of prescription a drug. *See, e.g.*, ¶¶ 3, 6-7, 137, 153, 159. Defendants should not be permitted to mischaracterize Plaintiffs' description of the AWP Scheme.

F. Plaintiffs Plead Fraud With The Particularity Required By Rule 9(b)

1. Rule 9(b) Pleading Standards

Rule 9(b) requires that "[i]n all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity." An exception to the particularity requirements of Rule 9(b) exists where plaintiffs are not directly involved in the alleged fraudulent scheme and, thus, cannot be expected to have personal knowledge of the facts constituting the fraud. *See Kuney Int'l, S.A. v. DiIanni*, 746 F. Supp. 234, 237 (D. Mass. 1990) (civil RICO claim was pled with sufficient particularity). In such cases, plaintiffs may satisfy Rule 9(b) by including those facts upon which their beliefs are found. *Id*; *see also United States ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d 39, 47 (D. Mass. 2001) ("[W]here facts underlying the fraud are 'peculiarly within the defendants' control,' a plaintiff may be excused from pleading the circumstances of the fraud with a high degree of precision.") (Saris, J.) (quoting *Boston & Me. Corp. v. Hampton*, 987 F.2d 855, 866 (1st Cir. 1993)).

This Court has previously referred to Rule 9(b)'s requirements as setting forth the "'who, what, when where, and how' of the alleged fraud." *Parke-Davis*, 147 F. Supp. 2d at 46 (quoting

United States ex rel. Walsh v. Eastman Kodak Co., 98 F. Supp. 2d 141, 147 (D. Mass. 2000)). The Complaint does exactly that.

2. Plaintiffs Allege Mail And Wire Fraud With The Particularity Required By Rule 9(b)

a. Plaintiffs Allege The AWP Scheme With Requisite Particularity

Plaintiffs satisfy Rule 9(b) where "[t]he general outline of the general scheme to defraud . . . provides the defendant with notice of the grounds on which the plaintiff's claim is based." *Kuney Int'l*, 746 F. Supp. at 237; *see also Hastings v. Fidelity Mortg. Decisions Corp.*, 984 F. Supp. 600, 607 (N.D. Ill. 1997) ("The [RICO] allegations must be specific enough to provide the defendants with a general outline of how the alleged fraud scheme operated and of their purported role in the scheme.").

Plaintiffs allege that Defendants inflate AWPs for drugs reimbursed under Medicare Part B and then market the spread between the Medicare reimbursement rate and the providers' acquisition cost. Through the AWP Scheme, Defendants incentivize providers to administer the drugs for which Defendants have created the biggest spread and, thereby, increase sales for the drugs and their market share. ¶¶ 4, 157-65. For brand name drugs administered outside the Medicare Part B context, Plaintiffs allege that Defendants specifically marketed the inflated AWP, the price on which Plaintiffs' payments are based, to PBMs and other intermediaries in order to induce them to place those drugs on their formularies. The AWP Scheme incentivizes intermediaries to place drugs on formularies based not on their professional judgment but, instead, on their desire to increase their profitability. Plaintiffs allege that PBMs and other intermediaries pocketed the "spread" between AWP and the actual cost paid for those brand name drugs. ¶¶ 5, 166-72.

Conceding that Plaintiffs plead the AWP Scheme with particularity as to Class 1, Defendants challenge Plaintiffs' allegations pertaining to Class 2, to wit, Defendants' actions directed at the private, third-party payor sector. Defs.' Mem. at 32-35. First, while many of the examples of AWP inflation provided in the Complaint have been documented for Medicare Part

B drugs, those same drugs are also sold in the private payor market and, consequently, the impact of the fraud is the same. Further, while Defendants list the purported scheme-related allegations that Plaintiffs have allegedly failed to provide, a cursory review of the Complaint reveals the "missing" allegations. For example, Defendants claim that Plaintiffs have failed to identify "the identity of a single 'brand name drug' manufactured by a single one of the multiple defendants that are subject to these allegations." Defs.' Mem. at 33. To the contrary, at the beginning of Section V of the Master Complaint, entitled "Examples of Specific Unlawful Conduct," Plaintiffs describe the specific unlawful conduct of each named Defendant in great detail. ¶¶ 183-328. Further, at the end of almost every Defendant-specific section, Plaintiffs provide specific examples of inflated AWPs for prescription drugs ***identified by name***. *See, e.g.*, ¶¶ 190 (Abbott); 209 (Aventis); 217 (Baxter); 223 (Bayer); 238 (BMS); 260 (GSK); 291 (Immunex); 306 (Pharmacia); and 323 (Sicor).

Defendants also claim that Plaintiffs have failed to identify "a single specific allegation about how a single health insurance plan or third party payor, including any of the named plaintiffs, was allegedly affected, let alone damaged, by the [AWP Scheme]," Defs.' Mem. at 33, yet many paragraphs do, *see*, *e.g.*, ¶¶ 329-32, putting Defendants on sufficient notice of Plaintiffs damage claims.

Defendants further assert that only ¶ 162 addresses Defendants' improper distribution of drug samples and other inducements and price reductions. Defs.' Mem. at 34.[28] But, on the contrary, the Complaint alleges, *inter alia*, that Defendants AstraZeneca, Baxter, Bayer, the BMS Group and Pharmacia each engaged in a form of this scheme to defraud. *See* ¶¶ 201, 218, 225, 244 and 302(e).

Defendants also claim that Plaintiffs have not provided "**a single specific allegation about how any defendant allegedly 'inflated' a brand name drug's 'AWP**,' or how a defendant allegedly 'marketed the spread' to a PBM." Defs.' Mem. at 33. Yet, not only do

[28] This is the only particularity challenge relevant to the Medicare Part B class allegations.

Plaintiffs set forth specific examples of inflated AWPs (*see, e.g.*, ¶¶ 190, 209, 217, 223, 238, 260, 291, 306, and 323), the Complaint alleges, *inter alia*, that:

- "AstraZeneca documents reveal that AstraZeneca was directly marketing the spread to physicians." ¶ 196; *see also* ¶ 197 ("[A]t the same time AstraZeneca was raising the AWP for Zoladex, it was lowering the real price to providers (by giving bigger discounts), which served to widen the spread.").

- An internal Baxter document admitted that "[i]ncreasing AWPs was a large part of our negotiations with large homecare companies." ¶ 213.

- Baxter circulated marketing and sales documents comparing the costs of their drugs to the costs of their competitors to induce physicians to use Baxter drugs to get larger "return-to-practice" amounts. ¶ 215.

- An internal Bayer document showed that Bayer believed it had to raise its AWP in order to obtain business from homecare companies and that doing so could be "done overnight." ¶ 220.

- An internal BMS Group document showed that BMS encouraged doctors to take advantage of the spread between the AWP and acquisition costs for its product Vepesid. ¶ 242.

- Internal documents show Glaxo's decisions to repeatedly increase AWP for its drug Zofran to compete with Kytril. ¶¶ 262-75. SKB did the same for Kytril. ¶¶ 277-81. Correspondence between the two companies show that both companies were aware that the other was competing on the basis of a significantly inflated AWP. ¶¶ 284-87.

- "The J&J Group created promotional materials and worksheets to allow them to market the spread between the published AWP and the actual selling price to doctors." ¶ 297.

- Internal documents show that Sicor Group had a marketing strategy to market its price spread to the top 40 AIDS hospitals. ¶ 320.

Moreover, the law does ***not*** require that Plaintiffs include ***every*** AWP for ***every*** drug for ***every*** Defendant. *See* Defs.' Mem. at 35. As the court stated in *Kuney Int'l*, "[t]he additional particularity desired by the defendant, regarding the exact role [he] played in the scheme to defraud . . . should be left for discovery and is not required to be alleged in the complaint under Rules 8 and 9(b)." 746 F. Supp. at 238; *see also Hastings v. Fidelity Mortg.*, 984 F. Supp. at 608 ("It is true that '***the scheme*** must involve some sort of fraudulent misrepresentations or

omissions . . .' but it is not necessary for every participant in the scheme to make them.") (citation omitted); *Venzor v. Gonzalez*, 936 F. Supp. 445, 449 (N.D. Ill. 1996) (denying motion to dismiss RICO claim; "[a]lthough the complaint does not always distinguish between defendants as precisely as it could have, ... we think that the allegations sufficiently spell out the fraud.") (citation omitted). Indeed, Defendants would require a level of detail not previously required by this Court under Rule 9(b), for this Court has previously rejected defense pleas that a plaintiff must allege every facet of a complex fraud:

> Defendant contends that the pleading of the basic scheme of fraud or the identification of certain instances of fraudulent conduct does not satisfy Rule 9(b). Indeed, Defendant goes so far as to argue that Rule 9(b) requires no less than the identification of every ineligible prescription submitted to the government for payment. This view of Relator's pleading obligation may fit a scenario where the alleged fraud is confined to a small number of transactions about which Relator had knowledge. However, where the alleged scheme of fraud is complex and far-reaching, pleading every instance of fraud would be extremely ungainly, if not impossible.

Parke-Davis, 147 F. Supp. 2d at 49.

Plaintiffs have more than satisfied their obligation under Rule 9(b) to "setting out a general scheme of fraud" and put Defendants on "notice of the grounds" on which Plaintiffs' claims are based. *Kuney Int'l*, 746 F. Supp. at 238. Defendants' cry that they "have no idea what the 'Class 2' 'brand name' PBM claims are all about" (Defs.' Mem. at 33) rings hollow.

b. Plaintiffs Allege With Particularity Defendants' Knowing Participation In The AWP Scheme

Plaintiffs are not required to allege that Defendants "knowingly" engaged in the fraud if it is obvious from the facts alleged that the acts were committed ***knowingly***. *See Corporacion Insular De Seguros v. Munoz*, 826 F. Supp. 599, 610 (D.P.R. 1993) (denying motion to dismiss RICO claim because "the Court fails to perceive how participation in the . . . enterprise alleged . . . could be anything but 'knowing.'"). Here, Plaintiffs allege Defendants' actual knowledge and also allege facts demonstrating that Defendants could not have engaged in the acts alleged without knowledge of doing so. Specifically:

- Defendants control the prices listed as the AWPs for each drug. ¶ 135. Defendants "knew and understood" that Plaintiffs and the Class used the *Red Book* and other publications to determine AWPs for drugs. ¶ 160. Because Defendants had such control over setting AWPs, they were able to set AWPs "that did not reflect the actual pricing structure of the drugs." *Id.*, ¶ 159.

- Defendants actively marketed the "spread" between AWP and a health care provider's actual cost in order to obtain market share. ¶ 171.

- Defendants instructed health care providers to bill for free samples, although they failed to calculate the provision of those free samples in their calculation of AWP. ¶¶ 162-64.

- Defendants provided other inducements to health care providers so that those providers would purchase Defendants' products based on the desire for those inducements, rather than based on their professional judgment. ¶ 165.

In addition, Defendants fraudulently concealed their actions which, of course, suggests that Defendants knowingly engaged in the acts that they concealed. *See* ¶¶ 173-76.

c. Plaintiffs allege with particularity Defendants' use of U.S. mail and interstate wire facilities in furtherance of the scheme

While courts in this Circuit require plaintiffs to allege the circumstances of the mail or wire fraud alleged, the requirement does not, as Defendants suggest, require Plaintiffs to describe every single act of mail or wire fraud that the wrongdoers allegedly committed. In the words of the First Circuit:

> Where there are multiple defendants, as here, and where the plaintiff was not directly involved in the alleged transaction, the burden on the plaintiff to know exactly when the defendants called each other or corresponded with each other, and the contents thereof, is not realistic. *Plaintiff here provided an outline of the general scheme to defraud and established an inference that the mail or wires was used to transact this scheme*; requiring plaintiff to plead the time, place and contents of communications between the defendants, without allowing some discovery, in addition to interrogatories, seems unreasonable.

New England Data Servs., Inc. v. Becker, 829 F.2d 286, 291 (1st Cir. 1987) (emphasis added); *see also Prudential Ins. Co. v. United States Gypsum*, 711 F. Supp. 1244, 1263 (D.N.J. 1989) (civil RICO plaintiffs need not plead the 'date, place or time' of the fraud, so long as they inject precision and some measure of substantiation into their allegations of fraud); *Center Cadillac v. Bank Leumi Trust Co.*, 808 F. Supp. 213, 229 (S.D.N.Y. 1992) ("[T]he complaint need not

specify the time, place and content of each mail communication ***where the nature and mechanics of the underlying scheme is sufficiently detailed***, and it is enough to plead the general content of the misrepresentation without stating the exact words used.") (emphasis added)).

Plaintiffs' Complaint describes in requisite detail the mechanisms of Defendants' AWP Scheme and describes how it was accomplished by acts constituting federal mail and wire fraud. Notably, the Complaint enumerates at least nine ways in which Defendants used the U.S. mails or interstate wire facilities to accomplish their scheme, including, *inter alia*, dissemination of marketing materials regarding the AWPs for drugs to providers; dissemination of AWPs and changes thereto to publishers; dissemination of checks for rebates, kickbacks and other financial inducements; and communication of fraudulent AWPs to the U.S. Government, insurers and consumers. ¶¶ 356, 383, 410, and 437. These allegations note the general contents of Defendants' communications and to whom they were sent and why. *Id.*

Moreover, where Plaintiffs allege that the fraudulent use of the mails and wires involved Defendants' own sales, research and marketing materials, courts find that many of the details are peculiarly within the knowledge of the defendants. *Sebago, Inc. v. Beazer East, Inc.*, 18 F. Supp. 2d 70, 80 (D. Mass. 1998) (finding that civil RICO plaintiff who alleged that defendant published two research reports distributed through mail had sufficiently pled mail fraud predicate acts); *Prudential Ins.*, 711 F. Supp. at 1263 (plaintiffs pled their RICO claims with sufficient particularity by alleging that defendants had "made representations in advertisements, sales literature, and trade publications that [the products at issue] were safe, nontoxic, fully tested, suitable for use in commercial buildings and desirable"). Here, Plaintiffs make similar allegations that Defendants marketed their products via similar means and have described the mechanisms of the AWP Scheme with sufficient particularity. *See, e.g.*, ¶¶ 356, 383, 410, and 437.

G. Plaintiffs Have Standing To Sue Defendants For RICO Violations

As required, Counts I, II, III and IV allege that Defendants' violations of federal law and their pattern of racketeering activity caused them and the members of Class 1 and Class 2 "to be injured in their business or property" because Plaintiffs and Class members "have paid many millions, if not hundreds-of-millions, of dollars in inflated reimbursements or other payments for Covered Drugs." ¶ 367; *see also* ¶¶ 394, 421, 448.

To establish standing to sue under RICO, Plaintiffs must allege some direct relationship between the injury sustained and the alleged racketeering activity (mail and wire fraud). *See Holmes v. Securities Investor Prot. Corp.*, 503 U.S. 258, 268-70 (1992); *Camelio v. American Fed'n*, 137 F.3d 666, 669 (1st Cir. 1998) ("When a plaintiff attempts to base a civil RICO claim on § 1962(c), that claim cannot succeed unless the injuries of which the plaintiff complains were caused by one or more of the specified acts of racketeering.") (footnote and citation omitted).

Under this analysis, and notwithstanding Defendants' arguments to the contrary (Defs.' Mem. at 22-25), the allegations of the Complaint are more than sufficient because Plaintiffs allege a direct connection between Defendants' AWP Scheme, their alleged acts of mail and wire fraud, and the multi-million dollar overpayments made by Plaintiffs and Class members. ¶¶ 367-369, 394-396, 421-423, 448-450. The Complaint alleges that Plaintiffs and Class members are the targets of Defendants' AWP Scheme. ¶ 3. The sole purpose of Defendants' pattern of racketeering activity (the alleged acts of mail and wire fraud) was to "deliberately overstat[e] the AWPs for their Covered Drugs, thereby creating a 'spread' based on the inflated figure in order to induce providers to prescribe their Covered Drugs to their patients and causing the Medicare program to pay an artificially-inflated rate of reimbursement for the Covered Drugs." ¶ 361. These allegations are more than sufficient to allege standing to sue under Section 1964(c) of RICO and satisfy the causation tests established by the Supreme Court in *Holmes*, 503 U.S. at 268-70. *See, e.g., Commercial Cleaning Servs., L.L.C. v. Colin Serv. Sys., Inc.*, 271 F.3d 374, 384 (2d Cir. 2001) (collecting cases); *Mid Atl. Telecom, Inc. v. Long Distance Servs.*, 18 F.3d 260, 263 (4th Cir. 1994). *Cf. Hamm v. Rhone-Poulenc Rorer Pharms.*, 187 F.3d 941, 952-53

(8th Cir. 1999), *cert. denied*, 528 U.S. 1117 (2000).[29] Moreover, there is no issue here of apportioning damages among Plaintiffs and Class members who have been harmed by the same injury. Plaintiffs allege injury to each of them and to each Class member: The amount of money that that person or entity paid out of pocket as a direct consequence of the AWP Scheme. ¶¶ 367-369, 394-396, 421-423, 448-450.

Given the facts and circumstances of this case, the RICO causation analysis offered by Judge Wolf of this District in *Sebago*, 18 F. Supp. 2d at 83-85, is particularly applicable. In that case, the plaintiff building owner and shopping center owner filed a class action against defendants, a distributor and fiberglass component supplier for the roof insulation that had been installed on the owners' roofs. The owners asserted civil RICO claims, contending that the roof insulation caused the owners' roofing systems to corrode, thereby causing injury to their "business or property." In response to defendants' motions to dismiss, the owners contended that they satisfied RICO's standing requirements because they alleged that defendants' misrepresentations and omissions constituted the proximate and factual cause of their injuries. *Id.* at 81. Rejecting defendants' claim that plaintiffs' RICO claims should be dismissed because the owners did not allege "reliance" upon the alleged predicate acts of mail and wire fraud, the alleged misrepresentations concerning the fiberglass insulation having been made to the plaintiff owners' predecessors, *id.* at 81-83, Judge Wolf stated that each element of RICO causation had been properly alleged:

> In the context of this case, these concerns weigh in favor of finding that the plaintiffs have standing to assert their RICO claim. Allowing [the plaintiff owners] to advance their RICO claims against these defendants will not create administratively inconvenient or unmanageable litigation. Nor will these plaintiffs' claims lead to duplicative recoveries. Finally, recognizing that these plaintiffs have standing will further RICO's statutory goal of encouraging directly injured victims to act as private attorneys general to vindicate the law. Here, the plaintiffs are owners of buildings allegedly damaged by latent defects of PFRI. Because of

[29] It should be noted that *Holmes* does not require that civil RICO plaintiffs must allege that they were the "targets" of defendants' scheme to defraud; however, that is one way to satisfy the standing requirements of Section 1964(c). *See BCCI Holdings (Lux.), S.A. v. Khalil*, 214 F.3d 168, 174 (D.C. Cir. 2000).

> the latent nature of the damage allegedly caused by PFRI, the former owner of [plaintiff] Sebago's building cannot reasonably be described as having been directly injured. Rather, the plaintiffs as present owners of buildings with alleged structural damage caused by PFRI's latent defects can be said to have been "truly injured in some meaningful sense." As such, allowing plaintiffs to press their claims here will further RICO's statutory goal of encouraging directly injured victims to act as private attorneys general to vindicate the law.

Id. at 83 (quoting *Holmes*, 503 U.S. at 279 (O'Connor, J., concurring).

Reading the allegations of the complaint, Judge Wolf found that the plaintiff owners had alleged that they were among the "intended victims" of the defendants' scheme to defraud. *Id.* at 83-84. Thus, assuming (as we must) that Defendants "have committed the acts alleged,"

> it is for a jury to apply the law of proximate ***causation*** and decide whether the plaintiffs were in the zone of foreseeable plaintiffs and whether the defendants' actions were a substantial factor in causing the plaintiffs' harm. *Peckham v. Continental Cas. Ins. Co.*, 895 F.2d 830, 837 (1st Cir. 1990) (holding that questions of ***causation*** "are normally grist for the jury's mill."); *Swift v. United States*, 866 F.2d 507, 510 (1st Cir. 1989) ("Application of the legal cause standard to the circumstances of a particular case is a function ordinarily performed by, and peculiarly within the competence of, the factfinder."); W. Prosser & W. Keeton, Prosser and Keeton on Torts 321 (5th ed. 1984) ("'proximate cause is ordinarily a question of fact for the jury, to be solved by the exercise of good common sense in the consideration of the evidence of each particular case.'") (citation and footnotes omitted). Thus, the court cannot properly rule as a matter of law that plaintiffs were outside the zone of foreseeable plaintiffs or that the defendants' actions were not a substantial factor. To the contrary, accepting the plaintiffs' allegations as true and drawing all reasonable inferences from them, it appears that both plaintiffs were among the intended victims of the alleged fraud. For purposes of these motions to dismiss, therefore, plaintiffs adequately plead ***causation*** and state a substantive RICO claim.

18 F. Supp. 2d at 85 (emphasis added).[30] The same principles apply in this case, and this Court should reject Defendants' contention that Plaintiffs do not properly alleged RICO standing.

[30] Defendants also argue that Plaintiffs should be barred from recovery because they are supposedly "indirect purchasers" of the Covered Drugs. Defs.' Memo. at 23. Even if it can be said that civil RICO liability "stops at the first victim," *Wooten v. Loshbough*, 951 F.2d 768, 770 (7th Cir. 1991), Plaintiffs allege that ***they*** are the "first" victims of the AWP Scheme; they are "out of pocket" as a consequence of Defendants' wrongdoing. *Blue Shield of Virginia v. McCready*, 457 U.S. 465, 475 (1982). In any event, the antitrust "indirect purchaser" doctrine does not bar Plaintiffs' claims against Defendants. *See Managed Care Litigation*, 185 F. Supp. 2d at 1319-20; *Iron Workers Local Union No. 17 Ins. Fund v. Philip Morris, Inc.*, 29 F. Supp. 2d 801, 823-24 (N.D. Ohio 1998).

H. Plaintiffs Properly Assert RICO Conspiracy Claims Against Defendants

Count I alleges a violation of RICO § 1962(d) because "each [Defendant] and each of the providers that were members of the AWP Enterprises ***conspired*** to conduct the affairs of such enterprises through [a] pattern of racketeering activity. . . ." ¶ 358 (emphasis added). In a footnote, defendants assert that Plaintiffs fail to allege that Defendants "knowingly" joined the conspiracy. Defs.' Mem. at 35 n.29. However, it is not necessary for Plaintiffs to allege that each of the Defendants "knew all the details or the full extent of the conspiracy, including the identity and role of every other conspirator." *Aetna*, 43 F.3d at 1562. Rather:

> All that is necessary to prove [a RICO conspiracy] is to prove that [defendant] agreed with one or more co-conspirators to participate in the conspiracy. Moreover, it is not necessary for the conspiratorial agreement to be express, so long as its existence can plausibly be ***inferred*** from words, actions, and the interdependence of activities and persons involved. In this case, the jury reasonably could have found that, although each defendant may not have known the entire sweep of the conspiracy, each defendant knew that he or she was a part of a larger fraudulent scheme. For example, since the evidence supported a finding that each of the Aetna defendants was well aware of the fraudulent business practices of Dexter and Cummings, the jury could find that all of the Aetna defendants knew they were part of a larger conspiracy in which other persons made uses similar to their own of fraudulent appraisals by Dexter, Cummings, or both.
>
> A defendant who does not know the "entire conspiratorial sweep" is nevertheless jointly and severally liable, in the civil context, for all acts in furtherance of the conspiracy.

Id. at 1562 (citation omitted) (emphasis added); *see also United States v. Boylan*, 898 F.2d 230, 242 (1st Cir. 1990).

Similarly, the Complaint alleges that each Defendant was aware of the AWP Scheme involving the fraudulent reporting of AWPs to the Publishers. Based upon these allegations, a jury can find that each Defendant knew that it was part of a larger conspiracy in which other companies made "uses similar to their own" of false and misleading AWPs. *Id.* Thus, under First Circuit precedent, Plaintiffs properly allege a RICO conspiracy claim against Defendants.

VII. PLAINTIFFS' STATE LAW CLAIMS ARE NOT PREEMPTED

Count V alleges that Defendants violated the consumer protection statutes of eleven states. ¶¶ 451-57. Defendants argue that (i) to the extent the Plaintiffs paid through the Medicare system, these state law claims are preempted by the Medicare Act and its regulations, and (ii) to the extent the Plaintiffs paid through an ERISA plan, the claims are preempted by the Employee Retirement Income Security Act ("ERISA"). Defs.' Mem. at 35. However, these challenges fail.

A. The Medicare Act Does Not Preempt Plaintiffs' Claims

In evaluating preemption, the "sole task" of a reviewing court is to determine the intent of Congress, *California Fed. Sav. & Loan Ass'n v. Guerra*, 479 U.S. 272, 280 (1987), beginning with the basic assumption that Congress ordinarily does ***not*** intend to displace state law. *See, e.g., Maryland v. Louisiana*, 451 U.S. 725, 746 (1981); *see also Massachusetts Ass'n of HMOs v. Ruthardt*, 194 F.3d 176, 178-79 (1st Cir. 1999). This is especially true where, as here, the claims involve an area traditionally regulated by the police power of the state such as the regulation of healthcare, including medical costs. *See Pennsylvania Med. Soc'y v. Marconis*, 942 F.2d 842, 846-7 (3d Cir. 1991); *Massachusetts Med. Soc'y v. Dukakis*, 815 F.2d 790, 791 (1st Cir. 1987) (the field of medical fee regulation seems by tradition to be one of state concern, and accordingly state laws regulating that area are presumed constitutionally valid); *Medical Soc'y of New York v. Cuomo*, 976 F.2d 812, 816 (2d Cir. 1992) (stating that the "regulation of public health and the cost of medical care are virtual paradigms of matters traditionally within the police powers of the state" and requiring "compelling evidence of an intention to preempt").

1. The Medicare Act Does Not Preempt The Field

Defendants' argument of field preemption is belied by three controlling precedents from the First, Second and Third Circuits. In *Massachusetts Med. Soc'y*, the First Circuit addressed the preemptive effect of Medicare Part B on state statutes regarding balanced billing and found that the federal statute demonstrated an explicit intent to ***minimize*** federal intrusion and ***not*** to preempt. *Id.* at 790-91. Similarly, in *Pennsylvania Med. Soc'y*, 942 F.2d at 846, the Third

Circuit held that Medicare Part B did not preempt state legislation regulating the medical billing practices. In *Medical Soc'y of New York*, 976 F.2d 816, the Second Circuit held that Medicare Part B had no preemptive effect on New York law capping physicians' fees. *See also Solorvano v. Superior Court*, 10 Cal. App. 4th 1135, 1146 (2d Dist. 1992) (holding that Medicare does not preempt state law fraud and unfair business practices claims).

Defendants errantly contend that Congress intended to occupy the field of Medicare drug reimbursement through a "pervasive, extensive and detailed" regulatory scheme. Defs.' Mem. at 36-37. To support their contention, Defendants again argue that Plaintiffs' seek to have state law define AWP, *see* Defs.' Mem. at 36-37, but as demonstrated *supra*, Plaintiffs merely seek to redress Defendants' wrongful scheme of deliberately ***inflating*** the AWPs of their drugs at the expense of Plaintiffs and the Class.

Moreover, the text of Medicare Part B reveals that it was not intended to displace state law because it lacks enforcement mechanisms for defrauded beneficiaries. In the absence of any federal remedy, "[i]t is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct." *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984) (finding that even though states are precluded from regulating the safety aspects of nuclear energy, state tort law remedies for personal injury are not preempted). In fact, the only sanctions specifically detailed under the Act explicitly preclude any preemptive effect by stating that the federal remedy is ***supplemented*** by sanctions available under state law. 42 U.S.C. § 1395 w-2. There is simply no indication that Congress intended to preclude the use of state law remedies for acts of fraud.

Courts also have found that, in passing the Medicare Act, Congress specifically intended to minimize federal intrusion into areas of state concern. *See Massachusetts Med. Soc'y*, 815 F.2d at 791. Indeed, the rights of citizens to bring consumer protection claims have long been established, and issues concerning health care, including health care fraud and the cost borne by consumers, have long been within the purview of the states. *Hillsborough County v. Automated Med. Labs., Inc.*, 471 U.S. 707, 719 (1985) (stating that "the regulation of health and safety

matters is primarily, and historically, a matter of local concern"); *Med. Soc'y of New York*, 976 F.2d at 816 (finding that the "regulation of public health and the cost of medical care are virtual paradigms of matters traditionally within the police powers of the state").

Furthermore, the Medicare Act has been the subject of constant review and modification since its passage in 1965. Since that time, Congress has never amended Medicare to take away from the states the rights to protect their citizens through common law fraud or consumer protection claims. *See Pennsylvania Med. Soc'y*, 942 F.2d at 850 ("[W]hen Congress remains silent regarding the preemptive effect of its legislation on state laws it knows to be in existence at the time of such legislation's passing, Congress has failed to evince the requisite clear and manifest purpose to supersede those state laws") (citations omitted). Thus, this silence is strong evidence negating Congressional intent to preempt.[31]

Like the defendants in *Massachusetts Med. Soc'y*, Defendants have failed to demonstrate a clear and manifest Congressional purpose to preempt state law. Both textual and case analysis compel the conclusion that Congress did not occupy the field covered by Medicare Part B to the exclusion of areas of traditional state concern, such as state deceptive trade practice statutes.

2. Plaintiffs' Claims Do Not Conflict with the Medicare Act

Defendants contend that Plaintiffs' state law claims conflict with the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 ("BIPA") because "plaintiffs are asking the Court under state laws. . . to substitute different AWPs." Defs.' Mem. at 37. The argument misrepresents the terms of BIPA and ignores the law on conflict preemption.

Conflict preemption exists when compliance with both state and federal law is impossible, or when a state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Crosby v. National Foreign Trade Council*, 530

[31] Nor does the one case cited by Defendants, *Congress of Cal. Seniors v. Catholic Healthcare West*, 87 Cal. App. 4th 491 (2d Dist. 2001), suggest otherwise. Defs.' Mem. at 37 n.31. First, unlike here, the case dealt with Medicare Part A, and not Medicare Part B. Second, the court's conclusion that federal law comprehensively occupied the field of Medicare provider cost reporting and reimbursement involved a vast web of statutes and regulations under Part A that are not present here. Third, Plaintiffs' claims do not require proof of a violation of a federal statute or a reexamination of agency rulemaking.

U.S. 363, 373 (2000). An actual conflict must exist for a finding of preemption; hypothetical or potential conflicts are insufficient. *See Rice v. Norman Williams Co.*, 458 U.S. 654 (1982).

Here, Defendants' preemption argument rests entirely on a misreading of BIPA. BIPA did not, as Defendants represent, "prevent HCFA from recasting AWP" or "prohibit HCFA from changing this system of reimbursement." Defs.' Mem. at 36. In fact, in BIPA Congress expressly authorized HCFA to "revise the payment methodology . . . for drugs and biologicals under part B of the medicare program" so long as it did so on the basis of recommendations following a GAO report. Defendants' Exhibit 16 at 160. BIPA sanctions HCFA review and alteration of the AWP system; it does not prevent it.

Moreover, nothing in BIPA can arguably conflict with the traditional police powers of the state to regulate health care and medical costs, or protect citizens from unscrupulous business conduct. Plaintiffs do not seek to substitute AWPs with arbitrary ones. Nor does requiring manufacturers to report accurate AWPs impede Medicare's objectives. To the contrary, it advances the objective of maintaining the financial integrity of the system.[32]

B. ERISA Does Not Preempt Plaintiffs' State Law Claims

Defendants contend that ERISA preempts the consumer protection claims of the plaintiff third-party payors, as well as the claims of individual Plaintiffs whose co-payments were made by an ERISA plan because, ostensibly, these state law claims "relate to" employee benefit plans. Defs.' Mem. at 37-40. Defendants misconstrue ERISA preemption law.

ERISA expressly preempts state laws that "***relate to*** any employee benefit plan." 29 U.S.C. § 1144(a) (emphasis added). Although courts have liberally interpreted the phrase "relate to" as meaning having a "connection with" or "reference to" an employee benefit plan (*see, e.g., California Div. of Labor Stds. Enforcement v. Dillingham Constr.*, 519 U.S. 316, 324 (1997)), "ERISA preemption is not inexorable." *Carpenters Local Union No. 26 v. United States Fid. & Guar. Co.*, 215 F.3d 136, 139 (1st Cir. 2000). In fact, the United States Supreme Court

[32] *See TAP Pharms. v. U.S. Dept. of Health & Human Services*, at 163 F.3d 199, 204 (4th Cir. 1998).

recognized that "relate to" was being interpreted well beyond that intended by Congress and consequently held that state laws that only ***indirectly*** relate to ERISA plans are not preempted: "***pre-emption does not occur . . . if the state law has only a tenuous, remote, or peripheral connection with covered plans, as is the case with many laws of general applicability***." *N.Y. State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 661 (1995) (quoting *District of Columbia v. Greater Washington Bd. of Trade*, 506 U.S. at 130, n.1) (emphasis added).[33]

The First Circuit's recent decision in *Carpenters Local* demonstrates the controlling distinction. The employees of a subcontractor (and their union) brought a state court action against a general contractor's surety to recover on a bond. 215 F.3d at 138. The claim arose because the subcontractor failed to make fringe benefit payments as required under Massachusetts' bond statute. *Id.*[34] The court reviewed several factors used to determine whether the law had a meaningful "connection with" with ERISA, namely whether the law (i) interferes with the administration of covered employee benefit plans; (ii) purports to regulate plan benefits; (iii) purports to impose additional reporting requirements; or (iv) regulates an area of the law traditionally thought to be the states' preserve. *Id.* at 141. Applying these factors, the court held that the bond statute did not have a meaningful "connection with" ERISA because the law had "no real bearing on the intricate web of relationships among the principal players in the ERISA scenario (*e.g.*, the plan, the administrators, the fiduciaries, the beneficiaries, and the employer)." *Id.* at 141. Furthermore, the statute did not "refer to" ERISA because the state law did not single out ERISA plans for special treatment and did not depend "on their existence as an essential part of its operation." *Id.* at 145.

[33] At issue was whether a state statute regulating hospital rates for inpatient care was preempted. The court found that "cost uniformity was almost certainly not an object of pre-emption, just as laws with only an indirect economic effect on the relative costs of various health insurance packages in a given State are a far cry from those 'conflicting directives' from which Congress meant to insulate ERISA plans." *Id.* at 662.

[34] The bond statute required the general contractor to post a bond covering labor and materials, including any indebtedness incurred by subcontractors for wages and fringe benefits. *Id.* at 139.

Applying *Carpenters Local* here demonstrates that Plaintiffs' state law claims do not have a "connection with" an employee benefit plan. With respect to the first three inquires in the *Carpenters Local* test, the consumer protection claims do ***not*** interfere with the administration of any employee benefit plan, regulate plan benefits or impose additional reporting requirements. Plaintiffs do ***not*** dispute the terms or scope of any benefit plan, seek to enforce benefits under ERISA plans, or claim that Defendants failed to provide benefits. To the contrary, Plaintiffs seek only to recover from Defendants co-payments fraudulently inflated by Defendants' AWP scheme in violation of consumer protection statutes. Any damages would come from Defendants and not from the plan itself. Thus, Plaintiffs' claims would not impact the structure of the plan nor have a demonstrable economic impact on the plan. Turning to the fourth prong, state consumer protection laws against fraud regulate "an area traditionally thought to be the states' preserve." *See, e.g., Trustees of the AFTRA Health Fund v. Biondi*, 303 F.3d 765, 775 (7th Cir. 2002); *LeBlanc v. Cahill*, 153 F.3d 134 (4th Cir. 1998).[35]

Nor do Plaintiffs' claims "refer to" ERISA per *Carpenters Local*. The relevant consumer protection laws do not single out ERISA plans for special treatment but apply generally to all fraudulent acts that harm consumers. Furthermore, consumer protection statutes do not depend on the existence of the ERISA plans as an essential part of their operation. Accordingly, ERISA does not preempt Plaintiffs' state law claims.[36]

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[35] Indeed, courts consistently permit state law claims by service providers against plans and insurers who pay plan benefits of plans who misrepresent coverage or the amount of benefits, wrongfully inducing health care providers to provide services. *See, e.g., In Home Health v. Prudential Ins. Co. of Am.*, 101 F.3d 600 (8th Cir. 1996); *The Meadows v. Employers Health Ins.*, 47 F.3d 1006 (9th Cir. 1995); *Lordmann Enters., Inc. v. Equicor, Inc.*, 32 F.3d 1529 (11th Cir. 1994); *Hospice of Metro Denver, Inc. v. Group Health Ins.*, 944 F.2d 752 (10th Cir. 1991); *Memorial Hosp. Sys. v. Northbrook Life Ins. Co.*, 904 F.2d 236 (5th Cir. 1990); *but see Cromwell v. Equicor-Equitable HCA Corp.*, 944 F.2d 1272 (6th Cir. 1991).

[36] Defendants cite *Harris v. Harvard Pilgrim Health Care, Inc.*, 208 F.3d 274 (1st Cir. 2000), for the proposition that ERISA preempts state law claims where the court must consult the terms of the ERISA plans to resolve plaintiffs' claims. Defs.' Mem. at 39 n.34. *Harris*, however, is inapposite because there, the court preempted a state action that could have interfered with the enforcement of the plan as against a participant. By contrast, no such "core" purpose is compromised here, where the plans are suing parties outside the ERISA plans to remedy fraud. *Harris* does not help revive Defendants' claim to ERISA preemption. Further, Defendants' argument that plaintiffs' claims are preempted because the court must consult the terms of the ERISA plans "to determine whether and how certain plaintiffs were injured" is baseless. Defs.' Mem. at 39. *See Stetson v. PFL Ins. Co.*, 16 F. Supp. 2d 28 (D. Me. 1998) (rejecting defendant's argument that fraud claim is preempted because determining the claim's validity required reference to the terms of employee benefit plan).

VIII. THE REMAINING ARGUMENTS MADE BY INDIVIDUAL DEFENDANTS DO NOT WARRANT DISMISSAL

In separate briefs, certain individual defendants have presented a potpourri of additional arguments in support of dismissal. Some, but not all, of these additional arguments have been addressed *supra*. Those that have not are addressed below.

A. Plaintiffs Have Standing To Sue All Defendants

Twenty-one (21) of thirty-seven (37) defendants[37] seek dismissal of all or some claims against them under the constitutional iteration of the standing requirement.[38] Each plaintiff has standing, and no claims should be dismissed for lack of standing.

1. The Constitutional Standard for Standing

To have standing a plaintiff must: (i) "demonstrate that he has suffered an 'injury in fact'. . . [that] must be concrete in both the qualitative and temporal sense," *Whitmore v. Arkansas*, 495 U.S. 149, 155 (1990); (ii) "satisfy the 'causation' and 'redressability' prongs of the Art. III minima by showing that the injury 'fairly can be traced to the challenged action' and [(iii)] 'is likely to be redressed by a favorable decision.'" *Id.* (quoting *Simon v. Eastern Kentucky Welfare Rights Org.*, 426 U.S. 26, 38, 41 (1976), and *Valley Forge*, 454 U.S. at 472); *see also American Postal Workers Union v. Frank*, 968 F.2d 1373, 1374 (1st Cir. 1992) (the "standing inquiry has three elements").

At the pleading stage, general factual allegations of injury resulting from the wrongful practice may suffice to establish standing. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992).

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[37] Standing arguments are raised by Defendants Abbott, Amgen, AstraZeneca, Baxter, Bayer, Berringer Group, GlaxoSmithKline, Hoffman-LaRoche, Immunex, Johnson & Johnson and related entities, Pfizer, Pharmacia, Sicor, Sicor Gensia and Warrick.

[38] In addition to its constitutional dimensions, "the doctrine of standing also embraces prudential concerns regarding the proper exercise of federal jurisdiction." *United States v. AVX Corp.*, 962 F.2d 108, 114 (1st Cir. 1992). No defendant appears to raise an argument of standing based upon prudential, as opposed to constitutional, concerns.

2. The Allegations Meet the Pleading Standards for Standing

Each individual and corporate plaintiff alleges an injury in fact that fairly can be traced to the challenged action of AWP fraud. Each individual alleges that he or she is a participant in the Medicare Part B system, received one or more pharmaceutical products through that system and incurred payments unlawfully inflated by Defendants. ¶¶ 13-22. Each corporate Plaintiff, too, alleges that it has been billed for and paid charges for covered drugs based on published AWPs. *See* ¶¶ 23-27. Nothing more is required for Article III standing.

The association plaintiffs also meet applicable standards. "The test for associational standing is – like the basic standing requirement – tripartite." *American Postal*, 968 F.2d at 1375. "The plaintiff association must show that (a) at least one of its members possesses standing to sue in his or her own right – *i.e.*, that the member can satisfy the three requirements of injury, tracability and redressability; (b) the interest that suit seeks to vindicate are germane to its purpose; and (c) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit" *Id.* (citations omitted); *see also Guckenberger v. Boston Univ.*, 957 F. Supp. 306, 320 (D. Mass.1997) (Saris, J).

Here, each of the 21 associations has alleged that one or more of its members has purchased prescription pharmaceuticals manufactured and/or distributed by Defendants has made inflated payments or co-payments in connection with those purchases, and were injured by the illegal conduct alleged in the Complaint. The associations also briefly describe their organizational purposes, and those purposes are consistent with the interests of this suit. *See, e.g.*, ¶ 28 (Citizens for Consumer Justice is a "Pennsylvania non-profit umbrella organization that promotes affordable, quality health care"); ¶ 29 (Citizen Action of New York is a "coalition of labor, senior citizen, women, student, tenant and community organizations that works with community activists for social and economic justice"). The allegations satisfy the tripartite test for associational standing for each associational plaintiff.

3. Defendants' Argument for More Specifics on Standing Lacks Merit

About half of the Defendants that raise a standing challenge acknowledge that one or more Plaintiffs have specifically identified a particular Defendant and/or its drugs as a source of injury,[39] but they persist with a standing challenge by seeking to have the claims of the ***other*** Plaintiffs dismissed as against them.[40] There is no requirement that every Plaintiff in these consolidated proceedings allege a purchase from every Defendant. The existence of one or more Plaintiffs who have provided the desired specificity is sufficient for standing purposes. *See Houlton Citizens' Coalition v. Town of Houlton*, 175 F.3d 178, 183 (1st Cir. 1999) (courts need not verify the independent standing of other parties when one of several parties, all of whom make similar arguments, has standing). The relief that these Defendants seek – an order limiting the claims against them to some-but-not-all of the Plaintiffs, and some-but-not-all of their drugs – apart from being unworkable, amounts to little more than an effort to de-consolidate these consolidated proceedings. At this stage of these MDL proceedings, nothing is to be accomplished by a series of rulings denominating which Plaintiffs are permitted to sue which Defendants for which drugs.[41]

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[39] Abbott Mem. at 1-2 (acknowledging that United Food and Commercial Workers Unions and Employers Mid West Health Benefits Fund ("UFCW") has a alleged "payment for an Abbott-manufactured drug"); Baxter Mem. at 1-2 (acknowledging that UFCW "alleges that it provided reimbursement for Baxter Therapies"); Boehringer Group Mem. at 4 (acknowledging that UFCW "has specifically alleged an injury fairly traceable to Boehringer"); GlaxoSmithKline Mem. at 1-3 (acknowledging that Teamsters Health & Welfare Fund of Philadelphia "THWF" has alleged purchase of a "prescription drug presently or formally manufactured by GSK"); Immunex Mem. at 2-3 (acknowledging that both UFCW and THWF alleged "payment for and Immunex-Marketed Drug"); Johnson & Johnson Mem. at 4-5 (acknowledging the purchase of Remicade, a drug manufactured by a J&J defendant); Pharmacia Group Mem. at 2-5 (acknowledging that both UFCW and THWF allege "that they paid for Pharmacia products"); SICOR Group Mem. at 1-3 (acknowledging that UFW alleges the purchase of one of SICOR's products"); Warrick Mem. at 1-3 (acknowledging that TCBW alleges a payment for Warrick-manufactured products).

[40] *See, e.g.*, Boeringher Group Mem. at 4 (seeking dismissal of "the claims of all plaintiffs save UFCW"); GlaxoSmithKline Mem. at 1 (seeking "an order limiting the claims against GSK to just one plaintiff asserting over payment to just one drug").

[41] While some Defendants acknowledge that certain Plaintiffs have specifically alleged purchase of that Defendant's drug(s), some Defendants still press dismissal of claims ***even as against that plaintiff*** by arguing that the Complaint fails to allege that those purchases were based on the AWP. *See, e.g.*, Abbott Mem. at 1-2. However, the Complaint specifically alleges that the "Third Party Payor Plaintiffs overpaid for applicable drugs based on, and in reliance on the, AWPs." ¶ 27.

The other Defendants that attack standing argue that the MCC fails to identify a specific Plaintiff that has purchased a specific drug manufactured by that Defendant. The argument fails for several reasons.

First, such specificity is not required at this early pleading stage particularly where, as here, the four third party payor Plaintiffs and the twenty-four associational Plaintiffs represent significant constituencies and have alleged purchases of Defendants' prescription drugs based upon inflated AWPs.[42] Second, submitted affidavits further demonstrate purchases from each Defendant of Defendants' products by Plaintiffs based upon AWPs, and accordingly have established requisite injury traceable to Defendants' challenged conduct.[43]

Third, the Complaint alleges a common practice among all Defendants by inflating AWPs in an effort to disguise kickbacks and other wrongful remuneration, and Defendants are thereby "juridically linked" purposes of this case. *See Payton v. County of Kane*, 308 F.3d 673, 678-680 (7th Cir. 2002) (six named plaintiffs that have direct claims against only two defendants nevertheless have standing to bring an action against all 19 defendants whose common course of action was juridicially linked); *see also Fallick v. Nation Wide Mutual Insurance Co.* 162 F.3d 410, 423 (6th Cir. 1998) (using juridical link analysis, the court concluded that once a plaintiff had established a claim against one of the named defendants, the rest of the determination about the suitability of class certification should proceed as usual under Rule 23, not as a matter of standing); *Moore v. Comfed Sav. Bank*, 908 F.2d 834, 838-39 (11th Cir. 1990) (it is appropriate to join as defendants even parties with whom the named class plaintiffs did not have direct

[42] At the pleading stage, general factual allegations of injury resulting from Defendants' conduct may suffice to establish standing. *Lujan v. Defenders of Wildlife*, 504 U.S. at 561. In this case, each of the four Third Party Payor Plaintiffs and each of the twenty-one non-profit association Plaintiffs, have hundreds or thousands of members that include members who have purchased prescription pharmaceuticals and made payments or co-payments and were injured by inflated AWPs. The fair inference is that Plaintiffs or their members have purchased drugs for all Defendants, just as the Complaint alleges.

[43] *See* Exhibits 3 to 26 attached to the Affidavit of Thomas M. Sobol. Defendants raise a standing challenge under both Rule 12(b)(1) and 12(b)(6). The First Circuit has not decided whether a motion to dismiss for lack of standing falls under rule 12(b)(1) or 12(b)(6). Compare *Sea Shore Corp. v. Sullivan*, 158 F.3rd 51, 54 (1st Cir. 1998) (standing as jurisdictional), with *Benjamin v. Aroostook Med. Ctr., Inc.*, 57 F.3rd 101, 104 (1st Cir. 1995) (standing analysis "differs little" from 12(b)(6) standard). A court may, however, receive evidence other than the allegations of a complaint when standing is challenged. *See New Hampshire Right to Life PAC v. Gardner*, 99 F.3d 8, 12 (1st Cir. 1996).

contact, and accordingly joinder by the court *sua sponte* of defendants that did not extend loans or otherwise have dealings directly with the plaintiff was proper under Rule 20); *Alves v. Harvard Pilgrim Health Care, Inc.*, 204 F. Supp. 2d 198, 205 (D. Mass. 2002) (Saris, J.) (citing *Fallick* and concluding that claims of ERISA beneficiaries could be maintained against two entities even though no plaintiff was a member of a plan with those entities).

In this case, it is ironic that Defendants themselves present the juridical link through their common defense that their collective actions are lawful and sanctioned by federal statute and/or regulation. Finally, Defendants' standing challenge really amounts to an attack on the representativeness or typicality of claims each named plaintiff as against them; those issues are far better dealt with at the Rule 23 stage.

B. ERISA Plans Are Proper Plaintiffs

Defendant Abbott asserts that the claims brought by plaintiffs Carpenters and Millwrights of Houston and Vicinity Welfare Trust Fund ("CMHV"), Teamsters Health & Welfare Fund ("THWF"), Twin Cities Bakery Workers Health and Welfare Fund ("TCBW") and United Food and Commercial Workers Unions and Employers Midwest Health Benefits Fund ("UFCW") should be dismissed under Rule 17(a), arguing that these plaintiffs are not real parties in interest with authority to bring suit on their own behalf. Abbott is wrong.

These four employee welfare benefit plans ("EWBP"s) are established and maintained pursuant to ERISA for the purpose of providing health benefits to eligible participants and beneficiaries. ¶¶ 23-26. Yet, EWBPs have the right to sue and be sued like other corporations and legal entities in non-ERISA contexts. *See* 29 U.S.C. §1132(d)(1); *Local 159 v. Nor-Cal Plumbing, Inc.*, 185 F.3d 978, 983 (9th Cir. 1999) (citing *Pressroom Unions-Printers League Income Sec. Fund v. Continental Assurance Co.*, 700 F.2d 889, 893 n. 8 (2d Cir. 1983)); *Int'l Union of Bricklayers & Allied Craftsmen, Local #1 v. Menard & Co. Masonry Bldg. Contractors*, 619 F. Supp. 1457, 1462 (D.R.I. 1985). Thus, although Abbott may be correct in stating that EWBPs are trusts, the whole crux of §1132(d)(1) in conferring legal entity status on

EWBPs is to "eliminate[] an artificial impediment to the prosecution of actions by such a fund . . . and thereby enhance[] an important purpose of ERISA: furtherance of the stability and integrity of [EWBPs]." *Int'l Union of Bricklayers*, 619 F. Supp. at 1462 (distinguishing *Carpenters & Millwrights Health Benefit Trust Fund v. Domestic Insulation Co.*, 387 F. Supp. 144, 147 (D. Colo. 1975).[44] Accordingly, the Court should reject Abbott's argument.

C. The Filed Rate Doctrine Does Not Apply Here

Defendants BMS and Braun contend that Plaintiffs' Class 1 claims are barred by the filed rate doctrine because the Medicare reimbursement rates at issue "were determined by the government." BMS Mem. at 1, 5; *see also* Braun Mem. at 1, 5-7. However, the filed rate doctrine does not apply here because the AWPs reported by Defendants were not filed with, approved or even reviewed by any regulatory body.

The filed rate doctrine prohibits a regulated entity from charging rates other than those "properly filed with the appropriate federal regulatory authority." *Arkansas La. Gas Co. v. Hall*, 453 U.S. 571, 577 (1981). The doctrine applies to industries that are statutorily required to file schedules of tariffs and rates with a regulatory body, such as public utilities, telecommunications, and shipping carriers. *See Town of Norwood v. New England Power Co.*, 23 F. Supp. 2d 109, 116 n.6 (D. Mass. 1998) (Saris, J.), *rev'd in part on other grounds*, 202 F.3d 408 (1st Cir. 2000). Information that is not "filed" with a governing regulatory agency pursuant to a legal obligation is not immunized under the filed rate doctrine and does not carry the force of law. *Comsource Indep. Foodservice Co. v. Union Pacific R.R.*., 102 F.3d 438, 442 (9th Cir. 1996) (holding that the filing of a tariff gives constructive notice of only those terms that are required to be filed in the tariff).

[44] Significantly, Abbot does not cite any authority that directly supports its proposition. *Lenon v. St. Paul Mercury Ins. Co.*, 136 F. 3d 1365 (10th Cir. 1998), did not address whether EWBPs were real parties in interest and/or could sue in their own right. Rather, the question was whether ERISA plans were trusts. As *International Union of Bricklayers* makes clear, though ERISA plans may be trusts, they still may sue and/or be sued. Indeed, even *Lenon* conceded that ERISA plans could sue in their own right and on their own behalf. *See Lenon*, 136 F.3d at 1370 ("We cannot see how the power of participants ***or the plans themselves*** to initiate civil actions in limited circumstances can deprive an ERISA plan of its status as a trust."). *Yale Fin. Servs. Trust v. Palmetto Tomato Packers, Inc.*, 1987 U.S. Dist. Lexis 10886 (N.D. Ill. Nov. 18, 1987), also relied on by Abbott, is distinguishable, as it did not involve an ERISA plan and thus did not call into question the construction of § 1132(d)(1).

Defendants do not file their AWPs with HCFA or any other government agency. First, Medicare reimbursement is based on publicly available published AWPs, not on any specific AWP filed with HCFA or any other regulatory body. Second, the Medicare Act does not require Defendants to file their AWPs with any regulatory body for approval; nor does the Act even require Defendants to submit AWPs to the *Red Book* or other industry compendia. Defendants admit this when they proclaim that "there are no regulations directing [them] to report AWPs to the services that publish them, let alone describing how AWPs are to be calculated." Defs.' Mem. at 4-5. Third, neither the HCFA nor the publishers of industry compendia review, even for accuracy, the AWPs reported by Defendants. *See* ¶ 135. Indeed, Defendants have gone to great lengths to keep the actual AWPs of their respective drugs secret and confidential. Thus, the filed rate doctrine cannot apply.

Knowing this, BMS and Braun attempt to concoct a new filed rate rule that no Court has ever endorsed. Without citing a single case, Defendants argue that the filed rate doctrine should apply by ***fiat*** to the Medicare Act because the doctrine purportedly applies to every regulated industry. *See* BMS Mem at 5; Braun Mem. at 5-6. However, the doctrine applies only to industries that are required to ***file*** schedules of tariffs and rates with a federal agency. *Town of Norwood v. New England Power Co.*, 23 F. Supp. 2d 109, 116 n.6 (D. Mass. 1998). Indeed, no court ever has applied the filed rate doctrine to Medicare because the reimbursement program has no such filing requirements.

BMS and Braun next contend that the doctrine should apply because Medicare Part B requires beneficiaries to pay a percentage of the "'allowed amount' set by Medicare," and that the AWPs constitute a filed rate. Defendant Braun appears to contend that the filed rate consists of the additional component of the 20% co-payment beneficiaries must make to purchase covered drugs. Braun Mem. at 5-6. This argument is easily refuted. The statute provides that the 20% co-payment is merely the beneficiary's fixed percentage of liability and not the amount of the reimbursement cost; it simply cannot constitute a rate or tariff filed with a federal agency.

In any event, the Complaint does not challenge the 20% co-payment amount. And, again, BMS and Braun ignore the fact that AWPs are not filed with a government entity.

Defendants' reliance on this Court's *Town of Norwood* decision is misplaced. Unlike here, *Norwood* involved a defendant utility company that ***had filed*** its rates and termination charges with the regulatory agency that had the exclusive legislative authority to determine whether the wholesale rates were "just and reasonable." 202 F.3d at 418. Nor does this case resemble *Servais v. Kraft Foods, Inc.*, 631 N.W.2d 629 (Wis. Ct. App. 2001), *aff'd*, 643 N.W.2d 92 (2002), cited by Braun as "strikingly similar" to the current situation. Braun Mem. at 7. That court found that the filed rate doctrine applied because the milk prices at issue were "established by a federal agency through formal rulemaking designed to implement a congressional scheme." *See Servais*, 631 N.W.2d at 634-35. The *Servais* court found highly persuasive that the federal government actually recommends minimum milk prices after a full review and public hearing into current economic and marketing conditions. *Id.* at 632-33. The AWPs that form the basis of Plaintiffs' claims undergo no such scrutiny.[45]

D. The State Action And Noerr-Pennington Doctrines Do Not Apply

Defendant BMS asserts that Plaintiffs' claims must be dismissed because Defendants are immune from liability under the related holdings in *Parker v. Brown*, 317 U.S. 341 (1943), and *Eastern R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961). BMS mischaracterizes those holdings and, in any event, the cases do not apply here.

In *Parker*, the Supreme Court held that "the Sherman Act did not apply to anticompetitive restraints imposed by the States 'as an act of government.'" *City of Columbia v. Omni Outdoor Adver., Inc.*, 499 U.S. 365, 370 (1991) (quoting *Parker v. Brown*, 317 U.S. at

[45] Other cases cited by Defendants are equally inapposite because they concern regulatory schemes that required regulated entities to file their rates with a government agency and receive approval from that agency before charging the filed rates. *See, e.g., Nantahala Power & Light Co. v. Thornburg*, 476 U.S. 953 (1986) (public utility required to file rates with the Federal Energy Regulatory Commission); *County of Stanislaus v. Pacific Gas & Elec. Co.*, 114 F.3d 858 (9th Cir. 1997) (public utility required to file rates with Federal Energy Regulatory Commission and California Energy Regulatory Administration); *Wegoland Ltd. v. NYNEX Corp.*, 27 F.3d 17 (2d Cir. 1994) (finding that a public telephone utility was required to file rates with the Federal Communications Commission); *Kline & Co. v. MCI Communications Corp.*, 98 F. Supp. 2d 69 (D. Mass. 2000) (same); *Cahnmann v. Sprint Corp.*, 961 F. Supp. 1229 (N.D. Ill. 1997) (same), *aff'd*, 133 F.3d 484 (7th Cir. 1998).

352). Simply put, the *Parker* state action doctrine is construed as creating an exemption or immunity from liability for "activities that might otherwise violate ***federal antitrust law***." *Earles v. State Bd. of Certified Pub. Accountants*, 139 F.3d 1033, 1040 (5th Cir. 1998) (emphasis added; citation omitted). Here, however, Plaintiffs have not asserted any antitrust claims, and Defendant has not pointed to one case in which any court has extended the holding of *Parker* state action doctrine beyond the antitrust context.

BMS also claims that it is immune from liability under the Noerr-Pennington doctrine – a doctrine that has its roots in the Supreme Court's holding in *Eastern R.R.*, and *United Mine Workers v. Pennington*, 381 U.S. 657 (1965). Under the doctrine, "antitrust liability cannot be predicated solely on petitioning to secure government action even where those efforts are intended to eliminate competition." *Armstrong Surgical Ctr., Inc. v. Armstrong County Mem'l Hosp.*, 185 F.3d 158 (3d Cir. 1999), *cert. denied*, 530 U.S. 1261 (2000). The doctrine is intended to protect the constitutional right to petition the government unless such activities are shown to be a mere sham. *See Eastern R.R.*, 365 U.S. at 137-38; *Bath Petroleum Storage, Inc. v. Market Hub Partners, L.P.*, 129 F. Supp. 2d 578, 592 (W.D.N.Y.), *aff'd*, 229 F.3d 1135 (2d Cir. 2000). As is the case with the *Parker* state action immunity doctrine, the Noerr-Pennington doctrine really is intended as an exemption from liability in the antitrust context.

However, assuming without conceding that the Noerr-Pennington can properly be applied as an exemption from liability in cases asserting RICO and state unfair and deceptive business practice claims, Noerr-Pennington immunity still would not apply here. Plaintiffs simply do not predicate their claims on any effort by Defendants to petition the government to take action. Noerr-Pennington immunity, therefore, does not apply.

E. Abbott's Assertions Concerning Reimbursement For Its Vancomycin Drug Are Misleading

Abbott asserts that one individual plaintiff could not have paid for vancomycin within the four-year statute of limitations because, according to Abbott, "Medicare ceased covering vancomycin on September 1, 1996." Abbott Mem. at 5 (citing 61 Fed. Reg. 66676, 66684 (Dec

18, 1996)). Abbott's contention ignores Plaintiffs' allegation of fraudulent concealment, which nullifies the four year statute of limitation, and, in any event, is wrong. While Medicare reimbursement for vancomycin "as a durable medical equipment infusion pump benefit" did end, *see* 61 Fed. Reg. at 66684, Medicare coverage for vancomycin administered intravenously by methods other than infusion pump remained in effect.[46]

F. Amgen's Assertions Concerning Reimbursement For Its Epogen Drug Are Misleading

Amgen seeks to mislead the Court regarding Epogen reimbursement, claiming that Epogen is not reimbursed by Medicare based on AWP but, rather, by a specifically established price. Amgen Mem. at 1. The statute cited by Amgen, 42 U.S.C. § 1395 rr (b)(11)(B)(ii), does state that Erythropoietin will be reimbursed at a set fee per 1,000 units when the drug is provided by a "provider of services, renal dialysis facility, or other supplier of home dialysis supplies and equipment." However the immediately preceding section, § 1395 rr (b)(11)(B)(i), states that when the drug is provided by a physician, it ***is*** reimbursed pursuant to the AWP system established by Medicare. Thus, any patient who is a Medicare Part B participant and receives Epogen from his physician will make his co-payment based on an inflated AWP. In addition, as plaintiffs have alleged, Amgen does state an AWP for Epogen, which is paid by non-Medicare Part B patients or their providers. Thus, numerous plaintiffs and Class members pay for Epogen, both in and out of the Medicare Part B context, based on AWP.

G. Plaintiffs Make Sufficient Allegations Of BMS's Intent To Defraud

BMS also asks this Court to find that, as a matter of law, BMS did not intend to deceive anyone when it stated AWPs for its drugs far above the prices it charged its customers. Yet, the Complaint specifically alleges each Defendant's fraudulent intent: "[Defendants] deliberately and intentionally published AWPs for Covered Drugs that did not reflect the actual pricing structure of the drugs, but was created solely to cause plaintiffs and the Class members to

[46] The relevant regulations cite "insufficient evidence to support the necessity of using an external infusion pump, instead of a disposable elastomeric pump or the gravity drip method, to administer vancomycin in a safe and appropriate manner." 61 Fed. Reg. at 66684.

overpay for the Covered Drugs." ¶ 159; *see also* ¶¶ 162-65. The Complaint also quotes BMS's own documents to not only negate the impermissible inference BMS wants the Court to draw, but to establish that BMS specifically intended, and knew, that Plaintiffs and Class members would use the inflated AWP as a basis for reimbursement:

> Currently, physician practices can take advantage of the growing disparity between Vepesid's list price (and, subsequently, the Average Wholesale Price) and the actual acquisition cost when obtaining reimbursement for etoposide purchases. If the acquisition price of Etopophos is close to the list price, the physician's financial incentive for selecting the brand is largely diminished." ¶ 242

BMS relies on a case under the False Claims Act, *US ex rel. Becker v. Westinghouse Savannah River Co.*, 305 F.3d 284 (4th Cir. 2002). There, a contractor was accused of filing false claims when it changed billing and accounting entries from one federal program account to another. The court noted that the contractor changed the entries exactly as directed by the Department of Energy. The Court then joined three other Circuits in finding that a claim made against the government is not "false" under the False Claims Act when the government is ***actually aware of the true facts*** at the time the claim is submitted. Thus, the court wrote, "the governments' knowledge of the facts underlying an allegedly false record or statement can negate the scienter requirement . . . ." *Id.* at 289. *Becker* does not help BMS here because, while the government established the AWP system, there is no evidence that the government, or anyone else, was aware of the true facts surrounding BMS's pricing of its drugs, or approved BMS's fraudulent inflation of its AWP's.[47]

Finally, BMS protests that it would be unfair to allow Medicare beneficiaries to recover when, ostensibly, the federal government itself has no claim for AWP manipulation. BMS offers no support for its assertion, and, as BMS well knows, there is a substantial likelihood that the government can recover. Indeed, the United States recently reached an $875 million criminal

[47] BMS concedes that reliance is not a required element of mail fraud in the First Circuit, but then cites a case that dismissed a RICO claim where the court found that a plaintiff's reliance was unreasonable because the true facts (real estate values and rental rates) were readily available to the plaintiff. *See United States v. Brown*, 79 F.3d 1550, 1559 (11th Cir. 1996).

and civil settlement with TAP pharmaceuticals regarding AWP manipulation, including the resolution of two False Claims Act suits against TAP. ¶¶ 155-56. More directly, BMS has acknowledged that it is currently the subject of a federal criminal investigation relating to AWP manipulation.[48]

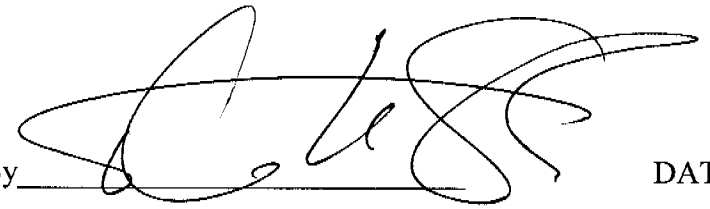
H. Plaintiffs Make Sufficient Allegations Against Defendant Hoffman-La Roche

Plaintiffs allege sufficient facts to state claims against Defendant Roche. Section IV of the Complaint alleges that Defendant Roche engaged in a fraudulent scheme along with every other Defendant. Plaintiffs use the plural to make a complicated factual scenario more comprehensive, not "to tar Roche with the alleged misdeeds of other defendants." *See* Roche Mem. at 4. That Plaintiffs list no "examples" specific to Roche in Section V of the Complaint is irrelevant. Roche also contends that Plaintiffs allege claims against them only as an "afterthought." *See* Roche Mem. at 2 and 5. The fact that Roche was first named in the Complaint and not in any underlying cases transferred by the MDL Panel is irrelevant to whether Plaintiffs state claims against Roche. Roche's earlier omission merely indicates that the investigation of the AWP Scheme is ongoing. Indeed, it is likely that other defendants may be added later.

[48] See BMS' Form 10-Q for the period ending June 30, 2002: "We, together with a number of other pharmaceutical manufacturers, also have received subpoenas and other document requests from various government agencies seeking records relating to its pricing and marketing practices for drugs covered by Medicare and/or Medicaid. . . . We are unable to assess the outcome of these investigations, which could include the imposition of fines, penalties and administrative remedies."

IX. CONCLUSION

For the foregoing reasons, Defendants' motion to dismiss should be denied.

By  DATED: December 5, 2002.

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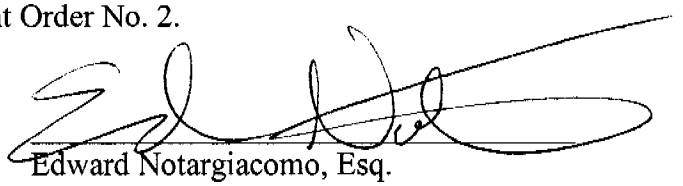
CERTIFICATE OF SERVICE

I hereby certify that I, Edward Notargiacomo, an attorney, caused a true and correct copy of the foregoing Plaintiffs' Consolidated Opposition to Defendants' Motions to Dismiss to be served on all counsel of record electronically on December 5, 2002, pursuant to Section D of Case Management Order No. 2.



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